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FEDERAL TRADE COMMISSION

**Agency Information Collection Activities; Comment Request**

**AGENCY:** Federal Trade Commission (“FTC” or “Commission”).

**ACTION:** Notice.

**SUMMARY:** The FTC is considering conducting a study to analyze the use and likely short- and long-run competitive effects of authorized generic drugs in the prescription drug marketplace. Before investigating these issues, the FTC is seeking public comments on its proposed information requests to firms in the prescription drug industry. The information collection requirements described below will be submitted to the Office of Management and Budget (“OMB”) for review, as required by the Paperwork Reduction Act (“PRA”) (44 U.S.C. 3501-3520).

**DATES:** Comments must be received on or before June 4.

**ADDRESSES:** Interested parties are invited to submit written comments. Comments should refer to “Authorized Generic Drug Study: FTC Project No. P062105” to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission/Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as prescribed below. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled "Confidential."<sup>1</sup> The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible.

Comments filed in electronic form should be submitted by clicking on the following weblink: <https://secure.commentworks.com/AuthorizedGenericStudy> and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the

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<sup>1</sup> Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

<https://secure.commentworks.com/AuthorizedGenericStudy> weblink. If this notice appears at [www.regulations.gov](http://www.regulations.gov), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it.

Comments should also be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC website, to the extent practicable, at [www.ftc.gov](http://www.ftc.gov). As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.htm>.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be addressed to Karen A. Goldman, Attorney, Policy Studies, Office of the General Counsel, 600 Pennsylvania Avenue, NW, Washington, DC 20580; telephone (202) 326-2574.

**SUPPLEMENTARY INFORMATION:** In the United States, the Food and Drug Administration (“FDA”) must approve the marketing of any pharmaceutical drug, whether brand-name or generic. The Hatch-Waxman Act establishes the regulatory framework under which the FDA may approve a generic drug to be marketed. Typically, a brand-name drug obtains FDA approval through a New Drug Application (“NDA”), and a generic drug manufacturer obtains FDA approval through an Abbreviated New Drug Application (“ANDA”) in which it may be allowed to rely on the clinical data first submitted by the brand-name drug manufacturer.

To encourage generic entry as soon as is warranted, the Hatch-Waxman Act allows generic drug manufacturers, in certain circumstances, to market a generic drug prior to the expiration of claimed patent protection for the corresponding brand-name drug. To be permitted to do so, a generic drug manufacturer must first submit a “paragraph IV” ANDA in which it certifies that (a) its generic drug will not infringe patents listed in the FDA’s “Orange Book” (“Orange Book patents”) as claiming the relevant brand-name drug product, and/or (b) the relevant Orange Book patents are invalid. If the paragraph IV ANDA leads to litigation, then 30 months after the litigation was filed (or after final decision in the litigation, if earlier), the FDA may authorize the marketing of the generic drug under the ANDA application.

At that point, the first-filed paragraph IV ANDA applicant becomes entitled to a 180-day marketing exclusivity period, during which the FDA cannot approve any other, later-filed paragraph IV ANDA for a generic drug corresponding to the same brand-name drug product. This protects the first FDA-approved paragraph IV ANDA applicant from competition with other ANDA applicants during this time.

The 180-day marketing exclusivity period does not preclude competition from NDA-approved “authorized generics,” however.<sup>2</sup> An authorized generic is chemically identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed in a generic version under the NDA-approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic. The trade dress typically differs for the brand-name drug and its authorized generic equivalent, but the drug product is exactly the same.

In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run, consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time.

Given the importance of generic drugs in lowering health care costs, Senators Grassley, Leahy, and Rockefeller have requested that the Commission conduct a study of “the short term and long term effects on competition of the practice of ‘authorized’ generics.”<sup>3</sup> In addition, Representative Waxman, one of the co-authors of the Hatch-Waxman Act, has requested that the FTC study “the impact of so-called ‘authorized generics’ on competition in the prescription drug marketplace.”<sup>4</sup>

The Commission proposes to undertake such a study, as described in this notice,

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<sup>2</sup> *Teva Pharm. Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

<sup>3</sup> See Letter to Chairman Deborah Platt Majoras, from Senators Grassley, Leahy, and Rockefeller (May 9, 2005).

<sup>4</sup> See Letter to Chairman Deborah Platt Majoras from Representative Henry A. Waxman (Sept. 13, 2005).

to examine both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers.<sup>5</sup> The study will be carried out pursuant to Section 6(b) of the FTC Act, 15 U.S.C. 46(b). Among other things, the proposed study will examine prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; business reasons that support authorized generic entry; factors (including product development and litigation costs) relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration; and licensing agreements regarding authorized generics. This information will enable the proposed study to make new contributions on the effects of authorized generic drug entry on prescription drug prices and, in particular, permit an evaluation of the impact of authorized generic drugs on the incentive offered by the period of 180-day exclusivity afforded to generic drugs that enter the market as the result of an ANDA with a paragraph IV certification.

Pursuant to 5 CFR 1320.8(d), the FTC published on April 4, 2006 a Federal Register Notice seeking comments from the public concerning the FTC's proposed study.<sup>6</sup> The comments and the Commission's responses to them are set forth below. Based on the comments, the Commission has revised the previously published information requests.

Generally, the Commission's revised Special Orders seek information on (i) authorized generic drugs (launched after Jan. 1, 2001) and all drugs related to them, i.e., brand-name versions of authorized generic drugs and all bioequivalent generic drugs; (ii) brand-name drugs that first faced generic competition after Jan. 1, 2001, for which at least one ANDA with a paragraph IV certification was filed, and all bioequivalent generic drugs;<sup>7</sup> and (iii) brand-name drugs for which at least one ANDA with a paragraph IV certification was filed after Jan. 1, 2001, and generic entry has not yet occurred. Within this general framework, the Commission has ensured that the requests are tailored to the needs of the planned study. For example, reflecting the widespread perception that the marketing of authorized generics increased markedly beginning in 2003, requests for generic company documents are generally limited to documents prepared after Jan. 1, 2003. In order to collect documents that underlie marketing strategies adopted in 2003, requests to brand-name companies seek documents prepared after January 1, 2002.

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<sup>5</sup> In its 2002 study of how generic drug competition prior to patent expiration has developed, the Commission found that the Hatch-Waxman framework had promoted entry by low-cost generic drugs prior to patent expiration. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>> (“*Generic Drug Study*”).

<sup>6</sup> Agency Information Collection Activities; Comment Request, 71 FR 16779 (April 4, 2006).

<sup>7</sup> Categories (i) and (ii) are likely to overlap substantially.

Similarly, the Commission has confined the study to drugs most likely to yield information necessary for evaluating the short- and long-run competitive effects of authorized generic drugs. Because no comprehensive list of authorized generic drugs is available, the Commission plans to identify the authorized generic drugs covered by the study via an initial, brief information request asking brand-name companies to identify their authorized generic drugs. The Commission will use those initial responses to develop subsequent Special Orders to generic and authorized generic companies that market authorized generic drugs. Based on a preliminary analysis, approximately 80 brand-name drug manufacturers, several authorized generic drug companies, and 100 generic companies will receive Special Orders. The revised Special Orders are set forth on the OMB website on information collection review, <http://www.reginfo.gov/public/do/PRAMain> and on the FTC's web page on the authorized generic study, <http://www.ftc.gov/os/comments/genericdrugstudy3/>.

Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the FTC is providing this second opportunity for public comment while requesting that OMB grant clearance for the proposed information requests. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before June 4.

### **Public Comments/Consultation Outside the Agency and Actions Taken**

The FTC received 13 comments on the proposed information collection requests.<sup>8</sup> All of the public interest organizations that submitted comments, which included a nonprofit group dedicated to the use of antitrust as a component of competition policy, strongly endorsed the study. For example, the American Antitrust Institute, CFA, FUSA, and USPIRG stated that by “initiating this study, the FTC has demonstrated its commitment to ensuring that the anticompetitive practices of brand name drug

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<sup>8</sup> The comments are available at <http://www.ftc.gov/os/comments/genericdrugstudy3/>. The 13 submissions are from AARP (nongovernmental organization for Americans age 50 and older); Actavis Group (Actavis) (generic pharmaceutical company); American Antitrust Institute, Consumer Federation of America, Families USA, and US Public Interest Research Groups (AAI/CFA/FUSA/USPIRG) (nongovernmental public interest organizations); Consumers Union (nonprofit organization representing consumers); Ronald W. Davis (Davis) (attorney submitting comments “on behalf of an undisclosed client”); Generic Pharmaceutical Association (GPhA) (trade association representing generic pharmaceutical manufacturers); Gilbert’s LLP (Gilbert’s) (law firm representing “one of the largest generic pharmaceutical companies in the United States”); IMS Health Inc. (IMS) (provider of information and research to the health care industry); Eli Lilly and Co. (Lilly) (an innovation-driven pharmaceutical company); Ohio Public Employees Retirement System (OPERS) (Ohio pension system); Pharmaceutical Research and Manufacturers of America (PhRMA) (trade association representing research-based pharmaceutical and biotechnology companies); Prasco, LLC (Prasco) (privately held, independent pharmaceutical company that makes AGs); and Prescription Access Litigation (PAL) (coalition of “consumer, healthcare, labor, senior, legal services, and women’s health organizations”).

manufacturers do not threaten Americans' access to low cost generic drugs."<sup>9</sup> Generally, the strong support of public interest organizations reflects their representation of consumers and retirees, and concern about the rising cost of pharmaceuticals.<sup>10</sup> Industry views, however, varied depending on whether the commenter was a marketer of AGs or in competition with marketers of AG drugs.<sup>11</sup>

Generic companies and their trade organization, GPhA, supported the study. GPhA "commend[ed] the FTC for taking initiative on this important issue. . . . This Study is no less critical than the FTC's earlier efforts on the generic drug front, such as the 2002 FTC study of generic pharmaceuticals, which led to a broad and nuanced perspective at an important time in the industry's history."<sup>12</sup> No generic drug company questioned the practical utility of the study. GPhA and one generic company commenter, however, asserted that the FTC's requests would be burdensome, and suggested that the FTC narrow or otherwise modify its request.<sup>13</sup> Generic company views on how to lessen the burden were somewhat variable, presumably because some generic companies market both ANDA-generic and AG drugs. Generic companies (and brand-name and AG companies) also urged the Commission to broaden the scope of the study by addressing a number of topics relevant to their marketing strategies.

Comments from the brand-name pharmaceutical industry, which markets or authorizes the marketing of AGs, generally accepted the core concepts of the study, but expressed concerns primarily focused on the breadth of the originally proposed document requests. The PhRMA comments, which were endorsed by Lilly, stated that the "proposed empirical study will show whether authorized generics benefit consumers by lowering prices for generic drugs," but also asserted that the proposed "information requests are overbroad."<sup>14</sup> Davis, apparently representing a brand-name pharmaceutical company, asserted that a very recent statutory change could sufficiently change the marketing of AGs to render a study based on recent historical data outdated.<sup>15</sup>

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<sup>9</sup> AAI/CFA/FUSA/USPIRG at 1. OPERS, AARP, PAL, Consumers Union, and GPhA also enthusiastically endorsed the study.

<sup>10</sup> See OPERS; AARP; PAL; Consumers Union.

<sup>11</sup> One industry commenter, IMS, submitted comments that only considered the possible use by the study of IMS' commercially available data.

<sup>12</sup> GPhA at 2.

<sup>13</sup> See GPhA at 5; Actavis at 1-2.

<sup>14</sup> PhRMA at 1, 7. See also Lilly at 1.

<sup>15</sup> See Davis at 9-11.

The FTC received only one comment from an independent authorized generic drug company; most AGs are either marketed by a subsidiary or division of a brand-name company or by a generic drug company under a license from a brand-name company. The independent AG drug company, Prasco, did not express a view of the study as a whole but rather commented on substantive issues that should be addressed, and ways to minimize burden.

As discussed below, the Commission has incorporated many of the suggestions to narrow the requests, especially for documents, which were the focus of the commenters' concerns about burden. In doing so, the FTC will avoid requesting information that is not necessary for the study and will substantially reduce the burden of the study. The Commission has not, however, adopted suggestions that would limit the study's usefulness. Indeed, the Commission has adopted a number of substantive suggestions that will enhance the utility of the study without imposing additional burden.

The following discussion of issues raised by the comments is organized into five sections: (A) the practical utility of the proposed study and why it is necessary for the proper performance of the FTC's functions; (B) suggestions to narrow the scope of the study; (C) suggestions to use alternative sources of information; (D) comments requesting limitations on the use of the information submitted; and (E) suggestions to broaden the scope of the study.

#### **A. Practical Utility of the Proposed Study and its Necessity for the Proper Performance of the FTC's Functions**

The Commission has proposed to obtain factual information that would provide a comprehensive picture of how generic competition is affected by the marketing of AG drug products.

**Comments:** Most comments stated that the proposed study will have practical utility, that it is necessary for the proper performance of the FTC's functions, or otherwise stressed the importance of the study. For example, Consumers Union stated, "We strongly believe that the collection of 'the information will have practical utility,' because we believe the data will show serious anti-competitive consequences of these arrangements."<sup>16</sup> GPhA stated that the study "will be crucial to a proper understanding of authorized generics, and is a prudent use of the Commission's resources."<sup>17</sup> AAI/FUSA/USPIRG asserted that "It is particularly important for the FTC to study authorized generics and other forms of anticompetitive conduct in the pharmaceutical market at this time, as over the next three years alone, prescription drugs worth over an

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<sup>16</sup> Consumers Union at 2.

<sup>17</sup> GPhA at 2.

estimated \$50 billion in U.S. sales will go off patent.”<sup>18</sup> PAL “commend[ed] the FTC for its decision to conduct this study. This information will be particularly useful as a tool for Congress to make an informed decision on whether further legislation needs to be adopted surrounding the marketing of authorized generics.”<sup>19</sup>

While acknowledging that the proposed study “should enhance public understanding of how authorized generics impact consumers,”<sup>20</sup> PhRMA asserted that some of the information sought by the proposed *document requests* would have little practical utility. PhRMA took this position because in its view the document requests were broader than necessary and would require the production of many documents unrelated to the topic of AGs.<sup>21</sup> Thus, PhRMA’s concerns about utility are a restatement of its concerns about burden. PhRMA did not assert that the proposed study and the planned report on AG drugs lacks utility. Davis, however, asserted that “the practical utility of the information [that the FTC proposes to collect] will be limited, because of a recent material change in the regulatory environment: the enactment of Section 6003 of the Deficit Reduction Act [“DRA”] of 2005.”<sup>22</sup> Davis stated that by changing the definition of the Medicaid “best price” to include AGs, Section 6003 will increase manufacturers’ Medicaid rebates<sup>23</sup> and thereby “fundamentally reduce the incentives of branded firms to introduce authorized generics.”<sup>24</sup>

**Response:** As discussed below, the Commission has addressed concerns about the

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<sup>18</sup> AAI/FUSA/USPIRG at 2.

<sup>19</sup> PAL at 6. *See also* OPERS at 1; AARP at 1 (supporting the proposed study).

<sup>20</sup> PhRMA at 2.

<sup>21</sup> *See* PhRMA at 14-15 (“The proposed document requests—by encompassing future competition documents, by focusing on documents unrelated or indirectly related to authorized generics, by reaching much deeper within the organizations than is customary, and by requiring a catalog of information relating to each responsive document—lack practical utility in light of the objective of this study.”) *See also* PhRMA at 2, 6, 9, 17; Lilly at 1.

<sup>22</sup> Davis at 3. Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171, amends Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)) to include in the manufacturer’s report of the best price and average manufacture price of sole source and innovator drugs pursuant to the Medicaid program, “all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act,” a requirement that would include AGs.

<sup>23</sup> Generally, manufacturers pay rebates to Medicaid that help to ensure that the price of drugs sold through the Medicaid program matches the generally available best price. In general, the rebate is equal to “the difference between the average manufacturer price and the best price . . . .” 42 U.S.C. 1396r-8(b)(3)(A)(ii)(I).

<sup>24</sup> Davis at 3. *See also* PhRMA at footnote 17 (discussing the possible effect of the Deficit Reduction Act’s provisions on incentives to market AGs).

breadth of the study by modifying the requests to ensure that they are limited to relevant documents.

Contrary to Davis' assertion, the available information indicates that the enactment of Section 6003 of the DRA will have little effect on the marketing of AGs. Section 6003 was enacted to increase brand-name pharmaceutical manufacturer Medicaid rebates to states by ensuring that AGs, as versions of brand-name drug approved under an NDA, are included in the Medicaid rebate calculation for sole source and brand-name multiple source drugs.<sup>25</sup> The price of an AG may be the best price available for a brand-name drug and, consequently, their inclusion may increase the Medicaid rebate. AGs are thought to be launched at the onset of generic competition, however, when brand-name sales drop off rapidly due to mandatory generic substitution requirements in most states' Medicaid programs.<sup>26</sup> Thus, the inclusion of AGs in the calculation of the best price is unlikely to substantially decrease brand-name company revenues for most drugs.<sup>27</sup> Indeed, the Office of the Actuary in CMS projected that the anticipated savings to the Medicaid program from Section 6003 are likely to be modest, a total of only \$229 million for both federal and state programs over a period of five years.<sup>28</sup> Accordingly, the FTC concludes that Section 6003 is unlikely to have a sufficient effect on the marketing of AGs to impair the practical utility of this study based on recent historical data. Nonetheless, the FTC has revised its Special Orders to include requests for information that will allow it to follow the marketing of AGs throughout 2007, after Section 6003 has gone into effect.

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<sup>25</sup> See 151 CONG. REC. S12069 (Oct. 31, 2005) (statement of Senator Grassley) (“My committee’s title also achieves savings by helping State Medicaid Programs obtain millions in payments owed by third-party payers each year. It also produces savings by ending drug manufacturers’ gaming of the system by closing the authorized generic loophole so that appropriate rebates are paid to the States.”). The amendment equalizes treatment of AGs by FDA—which treated them as branded drugs so that they could be marketed during the 180-day exclusivity period—and Centers for Medicare and Medicaid Services (CMS), which previously treated them as generic drugs for purposes of the rebate calculation.

<sup>26</sup> States use a variety of strategies to encourage the use of generic drugs in the Medicaid program, and “[s]ince 2000, there has been a steady trend toward increased mandatory generic substitution. In 2005, nearly all states . . . reported that they require generics to be dispensed when available.” THE HENRY J. KAISER FAMILY FOUNDATION, STATE MEDICAID OUTPATIENT PRESCRIPTION DRUG POLICIES: FINDINGS FROM A NATIONAL SURVEY, 2005 update (October 2005).

<sup>27</sup> Section 6003 might have a bigger effect on drugs that are particularly heavily used within the Medicaid program or must be dispensed without generic substitution and in states that do not have mandatory generic substitution requirements in their Medicaid programs.

<sup>28</sup> See Medicaid Program; Prescription Drugs; Proposed Rule, 71 FR 77174, 77190 (Dec. 22, 2006). See also U.S. CONG. BUDGET OFFICE, COST ESTIMATE: S. 1932, DEFICIT REDUCTION ACT OF 2005 35 (Jan. 27, 2006) (Table 15. Estimated Budgetary Effects of Title VI, Subtitle A—Medicaid, period from 2006-2010, projecting federal Medicaid savings of \$150 million).

## **B. Suggestions to Reduce Burden by Narrowing the Scope of the Proposed Information Requests**

Most comments concerning burdens focused on the document requests. Both brand-name and generic pharmaceutical companies asserted that the proposed document requests would be excessively burdensome, and proposed ways to limit the scope of the requests. By contrast, commenters generally did not express concern about burden due to requests for economic data, except regarding the request for cost data. They did not assert that the requests for sales and price data were excessive. As discussed in the following responses to the comments, the FTC has taken multiple steps to reduce substantially the burden arising from document requests, and it also has addressed concerns about cost data.

### **1. Comments on Document Requests**

#### **a. Request Documents Closely Related to Authorized Generics**

**Comment:** Both brand-name and generic pharmaceutical companies asserted that the FTC’s proposed document requests are too broad, and should be limited to documents that closely relate to AGs. PhRMA expressed concern about the large number of documents that could be required by the FTC’s “broad requests for documents that relate generally to competition between brand name and generic drug companies.”<sup>29</sup> PhRMA suggested that “document requests should be focused exclusively on those drug products for which a company has manufactured or licensed an authorized generic that has been sold in the marketplace,” because otherwise the response “would encompass large volumes of documents unrelated to authorized generics.”<sup>30</sup> Davis and PhRMA also suggested that tangentially relevant documents could be eliminated by deleting the phrase, “any documents” from the request for “any documents, including studies, surveys, analyses, and reports . . . that evaluated, considered, analyzed, or discussed how to respond . . . to . . . future or current generic competition . . . .”<sup>31</sup> Similarly, a generic pharmaceutical company, Actavis, asserted that the FTC’s proposed request to generic companies for “any documents, including studies, surveys, analyses, and reports . . . that evaluated, considered, analyzed, or discussed whether or how to proceed with generic

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<sup>29</sup> PhRMA at 2. *See also* PhRMA at 7-9.

<sup>30</sup> PhRMA at 8.

<sup>31</sup> *See* Davis at 13 (quoting 71 FR at 16781); *see also* PhRMA at 7. *See also* Davis at 4-7, 11-13 (expressing concern about the breadth of the study and suggesting that the FTC focus on “the central question”).

entry . . . .”<sup>32</sup> is too broad, because “[a]s a generic firm, most of Actavis’ documents will relate to whether or how to proceed with generic entry.”<sup>33</sup> Actavis also suggested eliminating the “any document” language and limiting the requests to final strategy documents.

**Response:** We have narrowed the proposed document requests by better tailoring them to focus on AG drugs. Accordingly, the FTC has eliminated the requests for documents relating generally to competition and generic entry, and rephrased all companies’ requests to focus specifically on AGs and issues arising from them.<sup>34</sup> In addition, consistent with the FTC’s previous Special Orders to the pharmaceutical industry, the “any document” language has been eliminated,<sup>35</sup> and the request has been revised to seek only high-level planning, decisional, and strategy documents.<sup>36</sup>

**b. Reduce the Document Requests by Focusing on Generic Company Documents**

**Comments:** PhRMA asserted that the study should focus on generic company documents, because “[t]he best documentary source for information on the costs and profitability of entry is generic drug company documents. The generic drug companies’ market analyses, studies, surveys, and reports will most directly respond to the core question of whether authorized generics have removed the companies’ financial incentives to enter.”<sup>37</sup> PhRMA also recommended that any request for brand-name company documents be limited to those that retrospectively analyze the effects of AGs on price competition and other matters, rather than consider future competitive strategies involving AGs. In PhRMA’s view, documents providing prospective analyses should not be required because they are subjective; consider the intent of brand-name companies, which is not relevant to whether patent challenges are profitable for generic companies;

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<sup>32</sup> Actavis at 2 (quoting 71 FR at 16782).

<sup>33</sup> Actavis at 3.

<sup>34</sup> See Brand-Name Drug Company Special Order, Item 27; Authorized Generic Drug Company Special Order, Item 10; and Generic Drug Company Special Order, Items 18, 19.

<sup>35</sup> See *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* at A-20 (July 2002) (requesting “all studies, surveys, analyses and reports.”); *PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES* A-2 (August 2005) (requesting “all business plans, strategic plans, planning documents, industry studies, analyses, and consultant reports . . .”).

<sup>36</sup> The request has not been limited to “final” documents, however, because of the difficulty of ascertaining what is “final.”

<sup>37</sup> PhRMA at 5.

and address events that may not have occurred.<sup>38</sup>

**Response:** The FTC will request the relevant documents of brand-name, AG, and ANDA-generic companies. While generic company documents may be the most informative as to generic companies' financial incentives to enter and challenge patents, documents from brand-name and AG companies, including prospective documents also, are relevant. Brand-name companies are sophisticated and knowledgeable market participants, and their strategies and views on the use of AGs should provide insight into the likely effects of AGs. The FTC will take into account the limitations expressed by PhRMA regarding documents that consider prospective matters in assessing the weight they should be accorded.

### c. Limit the Required Document Search

**Comment:** The FTC's proposed request asked for documents that "were prepared or received by or for any senior vice president (or equivalent position) with product line responsibility for the specified drug product or any officer(s) or director(s) of the company . . . ."<sup>39</sup> PhRMA suggested, however, that the documents requested by the FTC be limited to those "maintained in the files of current officers or directors."<sup>40</sup> PhRMA asserted that this would be consistent with the approach taken for previous FTC reports on competition in the pharmaceutical industry and with practices under the Hart-Scott-Rodino Act, and would "avoid confusion, reduce the burden, and focus the review on the most probative company documents."<sup>41</sup>

**Response:** The Commission believes that for the purpose of this study, which should cover decisions at the individual drug level as well as a company's general views on marketing AGs, it is necessary to consider documents at the level of product-line decisions as well as company-wide. However, to reduce the burden arising from this request, the Commission has limited the request for documents of senior vice presidents to documents maintained in their files. For the presumably smaller number of documents related to officers and directors, the Commission has retained the "prepared by or for" language. The Commission believes that this arrangement, plus the reduction in the number of drugs covered (discussed below), should reduce burden without jeopardizing the production of important, high-level, planning, decisional, and strategy documents. Moreover, depending on turnover, a request limited to the files of current officers and

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<sup>38</sup> See PhRMA at 3, 5, 9-11.

<sup>39</sup> 71 FR at 16781-2.

<sup>40</sup> PhRMA at 12.

<sup>41</sup> See PhRMA at 11; see also PhRMA at 12-13 (discussing Item 4 (c) of the Hart-Scott-Rodino notification report, FTC Form C4, rev. 06/06/06).

directors could eliminate all but the most recent documents. Such a limitation could impair the practical utility and quality of the information collected.

**d. Limit Sorting of Documents and Information about their Preparation**

**Comment:** PhRMA objected to the FTC’s requirement that companies indicate on each document “the date of preparation and the name and title of each individual who prepared the document, and group the documents by identified drug product.”<sup>42</sup> PhRMA asserted that this requirement will be very burdensome, and noted that sorting of documents is no longer required by the FTC in second requests in merger investigations.<sup>43</sup> Accordingly, PhRMA requested that companies be required to produce documents “as they are maintained in the regular course of business along with a list or index identifying the person whose files the document came from.”<sup>44</sup>

**Response:** The FTC believes that its ability to evaluate and analyze the information submitted in response to the Special Orders for this study would be greatly enhanced by a requirement to “group the documents by identified drug product.”<sup>45</sup> Eliminating this requirement could make it difficult to ascertain the relevance of many documents, and would slow analysis of the information by FTC staff. Given that the FTC has reduced the number of drugs covered by the requests (discussed below), sorting documents by drug should not be as burdensome as originally anticipated. Moreover, it is likely that information about different drugs is maintained separately in the regular course of business. The FTC recognizes, however, that some documents may generally address a topic, and relate to more than one drug. Accordingly, the FTC has modified the Special Orders to require all companies to group documents by identified drug product, and to respond separately regarding documents that discuss AGs generally.

The Commission believes that in most cases the date of preparation and the name and title of each individual who prepared the document will be evident from the document itself. However, to reduce burden, the FTC will require firms that respond to the Special Orders to specify only the name of the person from whose files the document came and whether the document was generated within the Company, or the name of the source if generated externally. This information should help the FTC determine the relevance of each document.

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<sup>42</sup> 71 FR at 16781.

<sup>43</sup> See PhRMA at 13-15.

<sup>44</sup> PhRMA at 14.

<sup>45</sup> 71 FR at 16781.

## 2. Comments on Matters Affecting Both Document and Data Requests

### a. Limit the Time Period Covered by the Request

**Comments:** The FTC's proposed request asked for documents dated after Jan. 1, 1998. GPhA and Actavis recommended that the FTC not seek documents from before Jan. 1, 2003, because the marketing of AGs, especially during 180-day exclusivity periods, began to increase around that time.<sup>46</sup> Moreover, Actavis asserted that older information is especially burdensome to obtain because it may be available only "in off-site storage facilities or on back-up tapes," and may exist in older formats and systems that companies no longer support.<sup>47</sup>

**Response:** To avoid imposing an unnecessary burden, the FTC has substantially reduced the period for which documents are being sought. The FTC agrees that generic company documents dated after Jan. 1, 2003 are likely to be the most useful for understanding the effects of AGs on generic companies' incentives to file ANDAs and to challenge patents via paragraph IV certifications. Therefore, we are changing the initial year for generic company documents from 1998 to 2003. The FTC's request for brand-name and AG company documents will be limited to those dated after Jan. 1, 2002, so that the reasons for any increased marketing of AGs beginning in 2003 might be ascertained.

The FTC also is reducing the time period covered by its data requests. Under the first Federal Register Notice, a data request potentially could have extended back until Jan. 1, 1999. To ensure consistency in reporting, the FTC is requesting sales and price data on brand-name, AG, and generic drugs after Jan. 1, 2001, or whenever marketing began. A request for this data is necessary to ensure the availability of sufficient comparison data on drugs for which no AG was marketed, to assess possible trends over time, and to examine possible correlations between sales or price levels and various business strategies such as patent challenges, marketing of AGs, and sharing of 180-day exclusivity.

### b. Reduce the Number of Drugs Covered

**Comments:** Both brand-name and generic drug companies suggested limiting the documents requested (and to some extent the data) by reducing the number of drugs covered by the study. PhRMA suggested that the FTC reduce the number of drug products covered by the study by limiting the sample for which information would be

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<sup>46</sup> See GPhA at 4 n.5; Actavis at 2.

<sup>47</sup> Actavis at 1-2. See also GPhA at 4 (noting that agreements to market AGs did not become prevalent until late 2003).

requested to those drugs for which an AG version has been marketed and a random stratified sample of other drugs, e.g., by studying a percentage of the drugs in various dollar sales ranges.<sup>48</sup> Actavis recommended that the FTC limit the request for documents to “drugs for which there was an AG launch or an announced agreement for an authorized generic launch.”<sup>49</sup> Davis also suggested limiting the drugs covered by the study by asking generic companies to identify drugs for which they did not file an ANDA because of concerns about competition from an AG, and initially request “relevant decisional documents as to these products.”<sup>50</sup> Prasco, on the other hand, appears to be concerned that by limiting the number of drugs or companies, e.g., by considering only drugs for which generic competition began with a period of 180-day exclusivity, the FTC might not examine the full range of situations in which AGs are marketed.<sup>51</sup>

**Response:** The FTC agrees that the number of drugs covered by the study should be reduced by focusing on AGs<sup>52</sup> and a limited number of other drugs necessary to illuminate the issues addressed by this study.

Accordingly, the Commission has limited the data requests to both brand-name and generic companies to (i) AGs and all related drugs, i.e., brand-name versions of AGs and bioequivalent ANDA-generic drugs; and (ii) brand-name drugs for which at least one ANDA with a paragraph IV certification has been filed, and all bioequivalent ANDA-

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<sup>48</sup> PhRMA at 8-9, 18-19. Note that PhRMA, which asserted that the FTC’s requests “would cover not only brand drug ‘products that have first faced generic competition since January 1, 1999’ but also products ‘that have received notice of the filing of an ANDA,’ misinterpreted the FTC’s Federal Register Notice and thus incorrectly believed that the study would cover a very large number of drugs. See PhRMA at 18 (quoting 71 FR at 16781). The FTC’s Federal Register Notice stated that “the brand-name companies to which the information requests would be sent include those companies with products that have first faced generic drug competition since January 1, 1999 or those that have received notice of the filing of an ANDA . . . .” 71 FR at 16781. Thus the criteria quoted by PhRMA refer to the *companies* that would receive notice, not the drugs that would be covered. These criteria would likely cover many companies, but the number of drugs for which each company will be required to provide data will be limited to AGs, brand-name and ANDA-generic versions of AGs, and drugs for which an ANDA with a paragraph IV certification has been filed. Thus, the number of drugs should not be large.

<sup>49</sup> Actavis at 2-3.

<sup>50</sup> Davis at 12.

<sup>51</sup> See Prasco at 2.

<sup>52</sup> Focusing requests on AGs is not straightforward because no comprehensive list of AGs is available. Thus, the first request proposed for this study is a request to brand-name companies to identify all AGs initially marketed after January 1, 2001. Although the FTC will provide a list of putative AGs (drugs for which an AG is believed to have been marketed) and drugs subject to ANDAs with paragraph IV certifications, the Special Orders assume that brand-name companies are better aware of drugs that have been marketed pursuant to their NDAs, and thus can identify their AGs, even if they are not on a list provided by the FTC.

generic drugs.<sup>53</sup> The data requests must address all such drugs so that the FTC has a complete and accurate basis upon which to evaluate relative prices, market shares, and sales levels sufficient to support paragraph IV patent challenges.

Moreover, the FTC recognizes that the scope of drugs necessary for purposes of document requests is narrower than the set of drugs needed to undertake a reliable economic analysis, which must include comparison drugs for which no AG was marketed. Consequently, document requests to brand-name companies have been modified to focus on documents that discuss specific AGs or related brand-name drugs identified by the brand-name company, or documents that generally discuss the marketing of AGs. Such documents should shed light on the brand-name companies' economic and strategic reasons for marketing AGs. The scope of document requests to generic drug companies, however, is not limited to drugs for which an AG has been marketed. Rather, to fully explore concerns that AGs are inhibiting generic entry and patent challenges, generic companies are required to submit documents that discuss AGs in regard to a decision to submit an ANDA and/or make a paragraph III or IV certification with respect to *any specific* drug, and documents that generally discuss AGs in regard to submission of ANDAs and/or making paragraph III or IV certifications, but not in regard to a particular drug. This approach takes account of the possibility that generic companies make decisions about whether to pursue marketing of a generic drug before it is known whether an AG will be launched, and thus relevant documents may concern drugs for which no AG has been marketed, drugs for which the generic company decided to file an ANDA with a paragraph III certification rather than a paragraph IV, or drugs for which the company decided not to file an ANDA.

### 3. Data

#### a. Quantitative vs. Qualitative Information

**Comments:** Brand-name pharmaceutical companies asserted that the study should be based primarily on quantitative information, rather than documents, while generic companies stressed the importance of qualitative information found in documents. PhRMA asserted that “data, rather than documents, best meet the needs of the study” because it believes that pricing and output data as well as data on generic entry in the presence of an AG will “show most clearly and directly whether authorized generics have benefited consumers by increasing availability of prescription drugs at lower prices.”<sup>54</sup> By contrast, generic companies argued that while quantitative data are useful for

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<sup>53</sup> These two groups are likely to overlap. Also, price data will not be requested regarding brand-name drugs for which an ANDA with a paragraph IV certification has been filed, but generic entry has not yet occurred.

<sup>54</sup> PhRMA at 2-3; *see also* Lilly at 1 (endorsing the comments of PhRMA on the scope and extent of the proposed request for information).

analyzing short-term effects of AGs, qualitative information is essential to gauge the extent to which AGs will affect generic drug entry decisions in the future.<sup>55</sup> Similarly, AAI/FUSA/USPIRG stated that “the more significant long-term effects will not be identified by current quantitative data” because the “more profound impact of authorized generics may be on the long-term incentive and ability of generic firms to engage in the costly and risky conduct of attempting to invent non-infringing drugs and challenge questionable patents.”<sup>56</sup>

**Response:** Quantitative and qualitative data are complementary, and both are necessary for a full exploration and analysis of the short- and long-term effects of AGs on competition in the prescription drug marketplace. Of the quantitative data that the FTC is seeking, price data show the short-term effects of AGs on consumers, while data on sales, market share, and return on investment are more relevant to the long-term effects of AGs on ANDA-generic companies’ incentives to file ANDAs and challenge patents. Quantitative data on recent filings of ANDAs with paragraph IV certifications should also be relevant to the long-term picture, because recent filings have been made in light of the current climate regarding the marketing of AGs.

Qualitative information, including company documents, however, is essential to evaluate the long-term effects of AGs on generic company decisions to file ANDAs and challenge patents. Generic company documents prepared before the first Federal Register Notice for this study was published are essential to interpret the quantitative data and to understand what factors or conditions, including AGs, might have contributed to any quantitative trends that we might observe. Generic company documents are also necessary to understand how AGs actually affect generic company decision-making. Brand-name company documents could further elucidate the likely effects of AGs on generic company decisions to challenge patents, and aid in the interpretation of the quantitative data.

#### **b. Cost accounting data**

**Comment:** PhRMA suggested that the FTC eliminate its request for cost accounting data from brand name firms because “cost accounting and margin data for brand name drug companies will not show whether generic entry has become unprofitable” and therefore such data are not useful for that analysis.<sup>57</sup> Similarly, Davis urged that the FTC drop its request for all cost data, because he believes that cost data are of limited relevance to the

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<sup>55</sup> See, e.g., PAL at 6 (“Much of the information concerning . . . longer-term effects is qualitative and narrative in nature, rather than quantitative.”); GPhA at 4-5 (data collection must include both quantitative and qualitative data).

<sup>56</sup> AAI/FUSA/USPIRG at 6.

<sup>57</sup> PhRMA at 17.

study and would be very burdensome to collect and analyze.<sup>58</sup>

Both PhRMA and Prasco, however, asserted that to evaluate whether AGs have deterred ANDA-generic entry, cost data from generic companies on the profitability of entry and return on investment are essential.<sup>59</sup> Prasco emphasized that the FTC should obtain data that would enable it to determine the “return-on-investment generated by generic products with and without competition from authorized generics,” and whether that return is a sufficient incentive for challenging patents.<sup>60</sup>

**Response:** The FTC agrees that the request for cost data from brand-name companies should be eliminated because it is not useful for evaluating generic companies’ incentives to file ANDAs and make paragraph IV certifications. Cost data regarding brand-name drugs will no longer be required.

Cost data regarding generic drugs, however, are necessary to evaluate the effects of AGs on profitability and return on investment, particularly during 180-day exclusivity. Thus, the revised requests require generic companies to submit cost data. Companies generate cost data in the ordinary course of business, so the request will not be excessively burdensome. To enhance uniformity and minimize burden, the FTC has modified the Special Orders to request the overall cost to manufacture, and has eliminated the request that companies separately provide data for cost subcategories, e.g., material cost, labor cost, manufacturing cost, distribution cost, API cost, and overhead cost. The FTC is also requesting generic companies’ costs for research and development and for paragraph IV litigation, to ensure that it can completely evaluate the investment necessary for generic entry that entails a patent challenge.

## C. Suggestions on Alternative Sources of Information

### 1. Comments on Holding Hearings

**Comment:** Several commenters, including GPhA, suggested that the FTC hold hearings to gather information on the likely long-term effects of AGs because they believe that the effects of AGs would not be reflected adequately in data on currently marketed ANDA-generic drugs, for which entry decisions and strategies may have been made before the

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<sup>58</sup> See Davis at 14.

<sup>59</sup> See PhRMA at 20; Prasco at 3.

<sup>60</sup> Prasco at 3.

marketing of AGs became more common in 2003.<sup>61</sup> Unlike the other commenters, however, GPhA also suggested that the FTC not use subpoenas: “[S]ubpoenas are an unnecessarily forceful mechanism by which to gather information, as many generic companies are interested in this issue and will be inclined to voluntarily submit information in response to FTC’s request.”<sup>62</sup>

**Response:** While the FTC recognizes the value of hearings for gathering information from industry and economic experts and enhancing our understanding of an issue, hearings cannot substitute for pre-existing, often confidential documents and data that can be acquired only by compulsory process. The use of Special Orders to gather pre-existing information was critical to the FTC’s reports on *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* (July 2002)<sup>63</sup> and *PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES* (August 2005).<sup>64</sup> As the FTC reviews the information it receives in response to the Special Orders, it will consider whether hearings should be held to supplement the responses with up-to-date views on particular issues.

## 2. Comments on the Requests for IMS Information

**Comments:** IMS, a provider of economic data on pharmaceuticals, asserted that rather than obtaining IMS data from individual companies, “the Commission could obtain information it seeks more efficiently by licensing the information directly from IMS.”<sup>65</sup> IMS believes that licensing would be more efficient because IMS data frequently are customized to a particular customer, and the FTC’s request could involve numerous companies. Accordingly, the FTC would likely receive data in inconsistent formats, which would not be comparable across “manufacturers, products, and time periods.”<sup>66</sup> IMS also suggested that the FTC eliminate its proposed request for “any other IMS data, or the equivalent thereof, used in the ordinary course of business,” because it is too broad

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<sup>61</sup> See GPhA at 1, 4, 6-7. See also AAI/FUSA/USPIRG at 6; PAL at 6; Gilbert’s at 2-3 (suggesting that the FTC hold hearings because the effects of AGs may not be reflected in pre-existing documents which “may show that generic companies have continued developing certain products despite the threat of authorized generics in the hope that the practice is curtailed by the courts, regulation or legislation”).

<sup>62</sup> GPhA at 5.

<sup>63</sup> Hereinafter *GENERIC DRUG REPORT*.

<sup>64</sup> Hereinafter *PBM REPORT*.

<sup>65</sup> IMS at 2.

<sup>66</sup> IMS at 2.

and would at least in part yield IMS information unrelated to the study.<sup>67</sup> Several pharmaceutical companies also suggested that the FTC obtain IMS data directly from IMS,<sup>68</sup> because “IMS Health sells its data under licenses that restrict licensees from disclosing the data to third parties.”<sup>69</sup>

**Response:** The FTC agrees that obtaining data directly from IMS would be more efficient, and would enhance the FTC’s ability to analyze and interpret the data. It would also reduce the burden on industry respondents, who would not have to find and produce this information. In addition, licensing data from IMS would facilitate obtaining complete data, especially retail-level sales and price data necessary for an evaluation of the effects of AGs on consumers.<sup>70</sup> Accordingly, the FTC has eliminated the requests for IMS information from the proposed Special Orders.

#### **D. Comments Requesting Limitations on Use of the Information Submitted**

**Comment:** GPhA requested that “the FTC give assurances that information gathered in conducting this study will be used solely for the purposes of the study.”<sup>71</sup>

**Response:** Although the purpose of the proposed information collection is to provide a basis for the proposed study, the Commission cannot give assurances that the documents and information collected will not be used for other purposes such as law enforcement investigations. The Commission would not exercise its enforcement authority solely on the basis of information collected in response to the Special Orders, however. Rather, it would do so only after gathering additional information from a company and/or other sources through an investigation separate from the proposed study. Also, although materials submitted may be covered by one or more stringent confidentiality constraints, the Commission cannot rule out that, under circumstances specified by law, the information could be used by other agencies for law enforcement purposes, by Congress,

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<sup>67</sup> IMS at 3-4. *See also* Prasco at 1-2 (suggesting that “IMS Integrated Promotional Services Total Promotion Reports” are unrelated to the topic of the study).

<sup>68</sup> *See* Actavis at 3; Davis at 14; PhRMA at 15-16.

<sup>69</sup> PhRMA at 15-16. IMS also stated that whether FTC obtains data from IMS directly or from individual companies, “IMS information constitutes confidential trade secret and commercial information that is protected from disclosure under section 6(f) of the FTC Act, 15 U.S.C. 46(f).” IMS at 3.

<sup>70</sup> *See* Gilbert’s at 3 (urging “the FTC to specifically request information on the pricing of drugs at the retail level, as this data may not be captured by the request as currently stated”).

<sup>71</sup> GPhA at 5.

or in judicial proceedings.

## **E. Suggestions to Broaden the Scope of the Proposed Study**

The FTC received a number of suggestions from generic, brand-name, and AG companies to broaden the scope of the study. Some of the suggestions addressed new topics not contemplated by the Federal Register Notice of April 4, 2006, and would require the submission of information not contemplated by that notice. Other suggested topics were more closely related to the proposed study and might require little or no additional information. Although the agency cannot be certain that it will be possible to address particular topics because the nature of the information to be collected cannot entirely be predicted, the Commission will make every effort to maximize the practical utility of the information it receives by using it to address as many issues relevant to the study as possible.

### **1. Topics Closely Related to the Scope of the Proposed Study**

**Comment:** Davis and PhRMA suggested that the FTC study take into account possible beneficial effects of AGs on generic companies that license them, e.g., from licensing revenues, by enhancing a company's portfolio of products, or by allowing a company to offer all dosages or strengths of a drug.<sup>72</sup>

**Response:** The FTC agrees that its study should encompass all aspects of the impact of AGs on generic companies, including both positive and negative effects. The Commission has revised its document requests to ensure that it is clear that information requests to generic companies extend to documents that discuss possible benefits to a company of marketing an AG drug.

**Comment:** Several commenters suggested examining a number of complex issues regarding the purposes, effects, limits, and necessity of 180-day exclusivity. Lilly suggested that the FTC analyze whether and to what extent consumers benefit from accelerated generic entry due to patent challenges; whether 180-day exclusivity undermines those benefits by delaying competition; and whether 180-day exclusivity is a necessary incentive for generic companies to undertake patent challenges.<sup>73</sup> Prasco suggested that the Commission assess whether the effects of AGs on competition differ from the effects of shared exclusivity by multiple first filers of ANDAs with paragraph IV

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<sup>72</sup> See Davis at 15-16; PhRMA at 20.

<sup>73</sup> See Lilly at 2.

certifications under the MMA.<sup>74</sup> Prasco also recommended that the FTC take into account the “apparent diminishing number of brand products available for paragraph IV ANDA challenges” when considering whether AGs have caused a decrease in the number of paragraph IV certifications.<sup>75</sup>

**Response:** These issues are related to the proposed study, and the FTC anticipates that the information to be obtained from companies and other sources may allow the Commission to address aspects of many of them. Such information includes price data, the timing of generic entry, dates of patent expiration, the extent of multiple entry, profitability, return on investment, and trends in paragraph IV certifications, and documents related to these issues. The Commission, however, will not broaden its information requests in order to expand the scope of its study beyond the previously announced analysis of the effect of AG drugs on competition.

## 2. Topics Outside the Scope of the Proposed Study

**Comment:** Several commenters suggested considering the full range of strategies that brand-name companies might use to delay generic entry and competition or otherwise promote the use of brand-name drugs at the expense of generics, regardless of whether the strategies involve AG drugs.<sup>76</sup> Practices suggested for inclusion in the study included the filing of citizen petitions or the use of the declaratory judgment system to delay generic entry;<sup>77</sup> the use of “product hopping” or other strategies to switch consumers from one brand-name drug to another at the onset of generic competition;<sup>78</sup> and the use of

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<sup>74</sup> See Prasco at 3. The MMA defined “first applicant” in such a way that all applicants who submit a substantially complete application containing a paragraph IV certification on the first day the FDA receives such an application may be granted 180-day exclusivity. See 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb). The MMA codified a policy that had been adopted by the FDA not long before the enactment of the MMA in 2003. See FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY (July 2003), available at <http://www.fda.gov/CDER/GUIDANCE/5710fnl.pdf>. Before that time, the FDA granted exclusivity on a patent-by-patent basis, so that two companies that were first filers with respect to challenges to different patents might share exclusivity for the drug product. See Letter from Gary Buehler, Office of Generic Drugs, FDA, to Diane Servello, Andrx Pharmaceuticals, Inc. (Nov. 16, 2001).

<sup>75</sup> Prasco at 3.

<sup>76</sup> See PAL at 6; AAI/FUSA/USPIRG at 5; Gilbert’s at 3; GPhA at 6.

<sup>77</sup> See AAI/FUSA/USPIRG at 4 (citizen petitions and declaratory judgment system); Gilbert’s at 3 (citizen petitions); GPhA at 6 (citizen petitions).

<sup>78</sup> See GPhA at 6 (product hopping); Gilbert’s at 3 (product switches); AAI/FUSA/USPIRG at 5 (product switches).

“reverse payments” and purportedly problematic patent settlements.<sup>79</sup>

**Response:** While the FTC appreciates the importance of studying strategies that might adversely affect generic competition, these topics are generally beyond the scope of the congressional request to study the competitive effects of AGs. Given finite resources, examination of these issues through expansion of the Special Orders would detract from the quality and timeliness of the study of AGs. To the extent that the study finds that AGs are marketed pursuant to the settlement of paragraph IV litigation, however, the FTC will examine the competitive implications of the arrangements as part of its ongoing review of such settlements.

**Comment:** Other commenters suggested that the FTC broaden the study to examine practices of generic pharmaceutical companies that might be anti-competitive and chill brand-name manufacturers’ incentives to innovate. In particular, Lilly suggested that the FTC examine “early and speculative patent challenges,” which “can have a chilling effect on innovation.”<sup>80</sup>

**Response:** The possible effects of early and speculative patent challenges and other practices on innovation are outside the scope of the congressionally requested study. An analysis of this complex issue, which would involve assessing innovation or measuring branded firms’ pharmaceutical research and development efforts, would detract from the FTC’s ability to carry out a complete and timely study of the effects of AGs on competition.

**Comment:** AARP suggested that the Commission broaden the scope of the study by “assess[ing] how different generics offer different levels of savings over the brand name drug; examin[ing] whether, in order to get better prices, consumers must search for a generic not produced by the manufacturer of the brand name drug; examin[ing] the cost impact of authorized generics on public programs, such as Medicare and Medicaid, and on private health insurance; and assess[ing] how the use of authorized generics impacts access to lower cost generic drugs, particularly for low-income individuals.”<sup>81</sup>

**Response:** The first suggestion, that the FTC assess the savings offered by different types of generic drugs relative to the brand-name drug, is within the scope of the proposed study and one that the Commission plans to address. The other topics,

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<sup>79</sup> See Gilbert’s at 3; AAI/FUSA/USPIRG at 5; PAL at 6.

<sup>80</sup> Lilly at 3. See also Davis at 15.

<sup>81</sup> AARP at 2.

however, are outside the scope of the congressionally requested study, which is designed to examine the short- and long-term effects of AGs on competition in the prescription drug marketplace, focusing on their impact on generic company incentives to market generic drugs and undertake patent challenges. The FTC does not anticipate addressing issues such as the impact of AGs on consumer behavior or specific classes of consumers, and on public or private programs not administered by this agency, because to do so would detract from the quality and timeliness of the congressionally requested study.

### **Destruction of Documents**

It should be noted that subsequent to this notice, any destruction, removal, mutilation, alteration, or falsification of documentary evidence that may be responsive to this information collection within the possession or control of a person, partnership or corporation subject to the FTC Act may be subject to criminal prosecution. 15 U.S.C. 50; *see also* 18 U.S.C. 1505.

### **Confidentiality**

The information presented in the study will not identify company-specific data. *See* 15 U.S.C. 57b-2(d)(1)(B). Rather, the Commission anticipates using primarily aggregated totals, on a level sufficient to protect individual companies' confidential information, to provide a factual summary of the effect of authorized generic entry since 1999. Section 6(f) of the FTC Act, 15 U.S.C. 46(f), bars the Commission from publicly disclosing trade secrets or confidential commercial or financial information it receives from persons pursuant to, among other methods, special orders authorized by Section 6(b) of the FTC Act. Such information also would be exempt from disclosure under the Freedom of Information Act. 5 U.S.C. 552(b)(4). Moreover, under Section 21(c) of the FTC Act, 15 U.S.C. 57b-2(c), a submitter who designates a submission as confidential is entitled to 10 days' advance notice of any anticipated public disclosure by the Commission, assuming that the Commission has determined that the information does not, in fact, constitute 6(f) material. Although materials covered under one or more of these various sections are protected by stringent confidentiality constraints, the FTC Act and the Commission's rules authorize disclosure in limited circumstances (*e.g.*, official requests by Congress, requests from other agencies for law enforcement purposes, administrative or judicial proceedings). Even in those limited contexts, however, the Commission's rules may afford the submitter advance notice to seek a protective order. *See* 15 U.S.C. 57b-2(c); 16 CFR 4.9 - 4.11.

### **Estimated Burden Hours and Labor Cost Burden**

In its prior Federal Register notice, the FTC estimated that a company's burden

for the AG study would range from 140 to 408 hours depending upon the number of a company's drugs covered by the study.<sup>82</sup>

Two commenters asserted that the FTC's estimates for complying with its document requests understated the burden hours. PhRMA, for example, asserted that "the FTC's estimates understate by several multiples the amount of time and money it would likely take to comply with the requests as written."<sup>83</sup> In contrast, the AG company Prasco had no "comment on the accuracy of the FTC's estimates" but noted that the "burden of providing the requested information can only be assessed in relation to the size of the company responding."<sup>84</sup> GPhA also did not comment on the FTC's estimates.

The initial hour burden estimates are consistent with previous PRA estimates and the FTC's experience with information requests that require financial data, answers to questions, and production of pre-existing documents. Even assuming, however, that due to the nature of the questions and the time frame covered in the first Federal Register notice, the FTC's initial estimate understated the burden, the Commission believes that its estimates are realistic given the modifications to the requests, which largely adopt industry suggestions for reducing burden. Previously, the study covered drug products that first faced generic competition after Jan. 1, 1999, for which an ANDA with a paragraph III or IV patent certification was filed. It now covers drugs subject to competition after Jan. 1, 2001, for which at least one ANDA with a paragraph IV certification was filed. Our preliminary review suggests that there are approximately 200 such drugs subject to generic competition, and that this set of drugs will also capture many of the AGs that have been marketed during this time frame.<sup>85</sup> The reduction in the number of drugs covered resulting from the changes in time frame and criteria for inclusion in the study should reduce the hour burden by more than one-half.

Other changes should reduce the burden even more. The time period covered by the document requests, which previously began on Jan. 1, 1998, now begins on Jan. 1,

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<sup>82</sup> 71 FR 16779, 16783 (April 4, 2006).

<sup>83</sup> PhRMA at 7. *See also* Davis at 11 (the FTC's Federal Register notice "materially underestimates the burden of compliance"). PhRMA did not comment on the Commission's burden estimates for complying with requests for financial data.

<sup>84</sup> Prasco at 2.

<sup>85</sup> In addition, to obtain a complete picture of industry practices in marketing AGs, we are asking companies to identify and provide information on all AGs (tablet or capsule form) that were launched after Jan. 1, 2001, regardless of what certifications were made regarding patents on the brand-name drug. Brand-name companies will also be requested to provide sales data on brand-name drugs for which at least one ANDA with a paragraph IV certification was filed after Jan. 1, 2001, and generic entry has not yet occurred.

2002 or 2003, depending on company type, and ends on April 3, 2006. This should reduce the burden of document production by more than half, and probably much more because older documents often are harder to obtain. Moreover, the document requests are now limited to planning, decisional, and strategy documents that specifically address AGs. Although any estimate of the expected decrease in burden due to the changes that focus the requests on AGs is necessarily imprecise because no complete list of AGs is available, the Commission believes, from preliminary information, that these changes alone should reduce the burden markedly.

Finally, the requests for IMS Health data and cost data from brand-name companies have been eliminated. The request for cost data from generic firms has been simplified by requesting annual operating statements. In sum, as a result of the combined effects of the changes to reduce the burden of both financial and document requests, the hour burden of the study should be a fraction of what it would have been pursuant to the requests of the first Federal Register notice.

After taking account of the public comments and the burden-reducing changes that we have made in response, the FTC believes that its previously published estimate of the total burden hours remains reasonable. The Commission has retained a three-tier estimate of burden hours depending upon the number of drug products for which a company is required to provide a response: companies with one to five drug products, companies with six to 10 drug products, and companies with more than 10 drug products. As before, the Commission anticipates that the majority of burden hours will result from document production. However, given that the Commission seeks only high-level documents strongly relevant to the AG study, the Commission has revised its burden estimates to reflect a greater amount of time spent on identifying responsive documents, and less time spent on retrieving and copying. The Commission has also increased its estimates of the maximum hours for these tasks to reflect the possibility that a few companies will have a relatively large number of drugs responsive to its requests.

Based on preliminary information, the FTC anticipates that it will seek information for 1 to 5 drug products from approximately 130 companies, 6 to 10 drug products from 20 companies, and for greater than 10 drug products from 40 companies. Thus, the cumulative hours burden to produce documents and prepare the response sought will be approximately 40,780 hours.  $[(138 \text{ hours} \times 130 \text{ companies}) + (230 \times 20 \text{ companies}) + (456 \text{ hours} \times 40 \text{ companies})]$  As previously discussed, the Commission anticipates that in general the number of drugs, and thus the number of burden hours, will

be proportional to company size.<sup>86</sup> The following table shows the estimated burden hours for different tasks for companies with different numbers of drugs covered by the study:

Task	1 - 5 Drug Products	6 - 10 Drug Products	> 10 Drug Products
Organize document and information retrieval	12 hours	24 hours	48 hours
Identify requested documents	40	80	200
Retrieve and copy requested documents	10	20	48
Identify requested financial information	40	50	60
Obtain financial information	12	16	20
Prepare response	24	40	80
Total	138 hours	230 hours	456 hours

It is not possible to calculate with precision the labor costs associated with answering the planned questions and producing the documents requested, because responses will entail participation by management and/or support staff at various compensation levels within many different companies. Individuals within some or all of those labor categories may be involved in the information-collection process. Nonetheless, the FTC has assumed that mid-management personnel and outside legal counsel will handle most of the tasks involved in gathering and producing the responsive information, and has applied an average hourly wage of \$250/hour for their labor. Thus, the labor costs per company should range between \$34,500 (138 hours x \$250/hour) and \$114,000 (456 hours x \$250/hour).

### **Estimated Annual Capital or Other Non-labor Costs**

The capital or other non-labor costs associated with the information requests will be minimal. Industry members should already have in place the means to store information of the volume requested. In addition, respondents may have to purchase office supplies such as file folders, computer CDs or DVDs, photocopier toner, or paper in order to comply with the Commission's requests. The FTC estimates that such costs will be minimal.

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<sup>86</sup> The Commission recognizes, however, that this may not apply to independent AG companies, for which a large fraction of the company's drugs may be covered. The FTC anticipates that there are few such companies, and that their responses are especially important to this study.

By direction of the Commission, Commissioner Harbour recused.

Donald S. Clark

Secretary