Supporting Statement for a Paperwork Reduction Act
Submission to OMB
FTC Study on Authorized Generic Drugs

The Federal Trade Commission (FTC or Commission) proposes to conduct an analysis of the effects of authorized generic drugs (AGs) on competition in the prescription drug marketplace. The Commission will seek the information for this study through compulsory process under Section 6 of the FTC Act, 15 U.S.C. § 46.

1. Necessity for Information Collection

The proposed collection of information is necessary for a congressionally-requested study of the likely effects on competition in the prescription drug marketplace of entry by authorized generic drugs. AGs are drugs that are identical to brand-name drugs approved under New Drug Applications[1] (NDAs), but typically are marketed under the drug's generic (active ingredient) name,[2] and are distributed through channels generally associated with generic drugs approved under Abbreviated New Drug Applications (ANDAs).[3] The issue is whether AGs reduce generic drug companies' incentives to challenge pharmaceutical patents and compete in the pharmaceutical market prior to patent expiration.[4]

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."[5] 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

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[1] *See* 21 U.S.C. § 355(b), (c).

[2] Sometimes, a trade name different from that of the brand-name drug is used. The National Drug Code number of the AG is also different from that of the brand-name drug.

[3] *See* 21 U.S.C. § 355(j). Generic drugs approved through the filing of an ANDA will be referred to as "ANDA-generic" drugs when necessary to distinguish them from AGs.

[4] Under the Hatch-Waxman Act, generic drugs may enter the market upon the expiration of patent protection on the brand-name drug, or in certain circumstances, prior to patent expiration if the generic company has challenged the validity of the patents or claimed that its drugs are noninfringing. *See* 21 U.S.C. § 355. ANDAs that challenge a patent on a brand-name drug must contain a "paragraph IV certification" asserting invalidity or noninfringement. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). To provide an incentive to generic companies to initiate such challenges and to market less expensive generic drugs as soon as is warranted, the Hatch-Waxman Act provides the first filer of an ANDA with a paragraph IV certification a 180-day exclusivity period during which other ANDA-generic drugs cannot be marketed. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I)(2004). AGs, however, are marketed pursuant to an approved NDA and thus can be marketed during the 180-day exclusivity period, reducing the value of any incentive derived from the exclusivity granted to the ANDA-generic manufacturer. *See* Teva Pharm. Indus., Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005).

[5] *See* Letter to Chairman Deborah Platt Majoras, from Senators Grassley, Leahy, and Rockefeller (May 9, 2005) (Appendix A, attached).

marketplace."[6]

Although the Commission has obtained some information on authorized generic drugs that have been marketed, no comprehensive list of such products is available.[7] Consequently, the Commission will rely primarily on requests to brand-name manufacturers to develop such a list. The Commission will use known information about the filing of ANDAs regarding brand-name products that first faced generic competition after January 1, 2001, or are subject to ANDAs filed after that date, to tailor each request to obtain information about specific drug products made by a particular manufacturer that have competed with generic drugs or will do so in the future. Based on information obtained from the FDA regarding relevant brand-name and generic drugs, the Commission proposes to send requests to approximately 80 brand-name drug companies, a small number of authorized generic companies, and 100 ANDA-generic drug companies.

2. How the Data Will Be Used

The FTC proposes to study company documents and financial data to assess the effects of AGs on competition. The FTC will obtain the information sought through interrogatories and document requests in Special Orders issued pursuant to Section 6(b) of the FTC Act, 15 U.S.C. § 46(b). Recipients of the Special Orders (information requests) will include brand-name pharmaceutical companies that have marketed authorized generic drugs and/or received notice of the filing of an ANDA with a patent challenge regarding a brand-name drug; generic drug companies that have filed ANDAs regarding those brand-name drugs, some of which companies also have marketed authorized generic drugs on behalf of brand-name pharmaceutical companies; and independent authorized generic drug companies that have marketed AGs.[8]

The information will be used to develop a report on (i) the short-term effects of AGs marketed during the 180-day exclusivity granted to the first generic company challengers to a patent on a particular drug, including effects on price, market share, revenues, profits, and return on investment; and (ii) long-term effects of AGs on generic companies' incentives to challenge patents. Qualitative information from company documents will inform the quantitative data obtained from companies and the FDA. Information in company documents is especially important for the assessment of long-term effects of AGs on generic companies' incentives and their likelihood of pursuing generic entry, which is central to the planned study. This complementary approach, relying on both quantitative and qualitative information, has been

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[6] *See* Letter to Chairman Deborah Platt Majoras from Representative Henry A. Waxman (Sept. 13, 2005) (Appendix B, attached).

[7] Minor adjustments to a drug's label, e.g. to indicate a distributor, do not raise safety or efficacy concerns, and thus the FDA allows manufacturers to notify it of such changes in the NDA holder's annual report. The FDA does not track whether the marketing of an authorized generic version of a drug or other marketing considerations prompt such changes. *See* Letter from William K. Hubbard, FDA, to Stuart A. Williams, Mylan Pharmaceuticals, Inc., and James N. Czaban, Heller Ehrman White & McAuliffe 5 (July 2, 2004).

[8] Proposed Special Orders to brand-name, generic, and authorized generic companies are attached as Appendices C, D, and E, respectively.

successfully used by the FTC in past reports. The report on AGs will be published by the FTC and made available not only to the Congressmen who requested the study but also to the public. Senators and Representatives may consult it in developing or considering legislation in this area.[9]

The documents and information collected could provide a basis for initiating a law enforcement investigation, but that is not the primary purpose of the study. The Commission will not exercise its enforcement authority solely on the basis of information provided by the companies in response to the proposed information collection request. Rather, it would do so only after gathering additional information from a company and/or other sources apart from the proposed study. The Commission would evaluate whether the evidence examined suggests unfair methods of competition.[10]

3. Information Technology

Improved information technology may assist in gathering and producing this information. Consistent with the aims of the Government Paperwork Elimination Act, 44 U.S.C. § 3504, the FTC will encourage respondents to submit as much data as possible in electronic form, and will provide electronic templates in which to enter the requested information. Database software also will be used to compile information and thereby facilitate review and analysis.

4. Efforts to Identify Duplication/Availability of Similar Information

There is no sufficiently comprehensive information available that can be used for these purposes. Efforts to identify duplicate sources of information included a review of published and unpublished studies and articles from industry, trade associations, governmental agencies, and academic researchers; news articles; and information available through the internet. The available information is not sufficient for the purpose of this study because it is not based on a comprehensive list of AGs, and does not rely on well-documented sources. Even the most comprehensive studies available are based only on AGs generally known to be on the market at one particular point in time. Such studies likely do not cover all drugs on the market even at that particular time. Moreover, the sales and price information that they present are incomplete or insufficient in various respects, e.g., retail prices are not presented, wholesale prices fail to account for rebates and discounts, or price information has not been appropriately weighted.[11] Finally, available sources are not based on pharmaceutical company internal documents, such as could be obtained by the Commission through compulsory process, and thus lack the insights that such documents might provide.

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[9] *See* S. 3695, 109th Cong. (2006) and H.R. 5993, 109th Cong. (2006) (bills "[t]o amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs").

[10] *See* FTC Act Section 5, 15 U.S.C. § 45.

[11] *See* IMS Consulting, Assessment of Authorized Generics in the U.S., spring 2006 (prepared for PhRMA); Aidan Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices, July 31, 2006.

The Commission is requesting data on cost, sales, and prices directly from manufacturers because other sources are either inadequate for a number of reasons, or are not accessible to the Commission. Cost information is not available from any other source, and must be obtained by compulsory process. Commercially available sales and price data are inadequate because they have not been adjusted for manufacturer rebates.[12] Although pursuant to the Medicaid program, manufacturers are required to report the Average Manufacturer Price (AMP) of their drugs to the Centers for Medicare and Medicaid Services (CMS), by statute the CMS cannot disclose historical information except to the Comptroller General or the Congressional Budget Office.[13]

Sales and price data must be obtained directly from manufacturers to ensure consistency in the definitions applied to these terms, so that relative price and market share calculations are accurate. The Commission's focus on this study is on the financial incentives for manufacturers to market generic drugs, and thus the Special Orders require that manufacturers submit the "total sales, net of discounts, rebates, promotions, returns and chargebacks."[14] In contrast, when reporting to the CMS, manufacturers do not always reduce their AMP values for rebates paid to pharmacy benefit managers because the issue of how to treat such rebates has not been resolved.[15]

Finally, the FTC will not require respondents to provide any documents that have been previously submitted to the Commission pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"),[16] although responding companies will be required to identify any such documents.

5. Efforts to Minimize the Burden on Small Organizations

The information collection request is not likely to impose an undue burden on small entities, such as small generic drug companies. Generally, the number of drugs about which a

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[12] Also, although some other government agencies obtain price information by subscription, such commercial data are not available to the FTC under the terms of the licenses.

[13] *See* 42 U.S.C. § 1396r-8(b)(3)(D) (2004). Section 6001(b)(2)(C) of the Deficit Reduction Act of 2005, P.L. 109-171, provides for the public availability of AMP after July 1, 2006. This provision has not yet been implemented, and in any case will not provide the historic information necessary for this study. *See* Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174, 77,186 (Dec. 22, 2006).

[14] This definition is based on that used for calculation of the manufacturer's average sales price under Medicare Part B. *See* 42 U.S.C. § 1395w-3a(c)(3) (manufacturer's average sales price is calculated net of "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates . . . .").

[15] *See* OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, DETERMINING AVERAGE MANUFACTURER PRICES FOR PRESCRIPTION DRUGS UNDER THE DEFICIT REDUCTION ACT OF 2005 5-6 (May 2006) (neither the statute nor the rebate agreements with CMS address how rebates to PBMs should be treated when reporting the AMP); *see also* 42 U.S.C. § 1396r-8(k)(1); GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID DRUG REBATE PROGRAM: INADEQUATE OVERSIGHT RAISES CONCERNS ABOUT REBATES PAID TO STATES, GAO-05-102 (Feb. 2005).

[16] *See* P.L. 108-173, tit. XI, Subtit. B, § 1112, 117 Stat. 2066, 2461-2 (2003).

company will be asked to provide information will be proportional to a company's size. In other words, the more drug products specified in the information collection request, the less likely that the respondent will be a small business. Based on initial information obtained from the FDA, the brand-name and generic drug companies with the largest number of drug products for which information will be sought are not small businesses. Independent AG companies, which the Commission anticipates will provide information essential to the understanding of AGs, may be an exception to the rule that the burden will be proportional to a company's size, because AG drugs make up a large percentage of their products. The FTC is only aware of one such company, however, and will consider possible modifications to avoid any undue burden on small entities based on the specific factual circumstance.

6. Consequences to Federal Program and Policy Activities/Obstacles to Reducing Burden

If the information is not collected, the FTC will not be able to prepare a well-documented study of how AGs affect short- and long-term competition in the pharmaceutical industry. The Commission believes that the proposed study will enable it to provide a comprehensive picture not only of how AGs affect competition, but also of the incentive to challenge pharmaceutical patents provided by the 180-day exclusivity period, and the value to consumers of generic entry resulting from such challenges. The collection is not a repetitive, periodic collection. One update requested by the Commission is necessary, however, to evaluate whether certain changes in the law effective Jan. 1, 2007, affect the marketing of AGs.[17] This update requests only the basic information necessary to identify and track AGs released during 2007. As described in the responses to the comments, the Commission has minimized the paperwork burden of the primary request by carefully limiting it to the information necessary for the study.

7. Circumstances Requiring Collection Inconsistent with Guidelines

The collection of information in the proposed survey is consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

8. Public Comments/Consultation Outside the Agency and Actions Taken

As required by 5 C.F.R.§ 1320.8(d), the FTC published a notice seeking public comment on the proposed collections of information.[18]

The FTC received 13 comments on the proposed information collection requests.[19] All of

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[17] *See* the discussion of Section 6003 of the Deficit Reduction Act of 2005 in the responses to comments.

[18] *See* Agency Information Collection Activities; Comment Request, 71 Fed. Reg. 16,779 (April 4, 2006).

[19] 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

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 manufacturers do not threaten Americans' access to low cost generic drugs."[20] Generally, the strong support of public interest organizations reflects their representation of consumers and retirees, and concern about the rising cost of pharmaceuticals.[21] Industry views, however, varied depending on whether the commenter was a marketer of AGs or in competition with marketers of AG drugs.[22]

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."[23] 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.[24] 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

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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").

[20] AAI/CFA/FUSA/USPIRG at 1. OPERS, AARP, PAL, Consumers Union and GPhA also enthusiastically endorsed the study.

[21] *See* OPERS; AARP; PAL; Consumers Union.

[22] One industry commenter, IMS, submitted comments that only considered the possible use by the study of IMS' commercially available data.

[23] GPhA at 2.

[24] *See* GPhA at 5; Actavis at 1-2.

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."[25] 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.[26]

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."[27] GPhA stated that the study "will be crucial

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[25] PhRMA at 1, 7. *See also* Lilly at 1.

[26] *See* Davis at 9-11.

[27] Consumers Union at 2.

to a proper understanding of authorized generics, and is a prudent use of the Commission's resources."[28] 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 estimated $50 billion in U.S. sales will go off patent."[29] 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."[30]

While acknowledging that the proposed study "should enhance public understanding of how authorized generics impact consumers,"[31] 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.[32] 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."[33] Davis stated that by changing the definition of the Medicaid "best price" to include AGs, Section 6003 will increase manufacturers' Medicaid rebates[34] and thereby "fundamentally reduce the incentives of branded firms to introduce authorized generics."[35]

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[28] GPhA at 2.

[29] AAI/FUSA/USPIRG at 2.

[30] PAL at 6. *See also* OPERS at 1; AARP at 1 (supporting the proposed study).

[31] PhRMA at 2.

[32] *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.

[33] 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.

[34] 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).

[35] 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).

Response: As discussed below, the Commission has addressed concerns about the 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.[36] 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.[37] Thus, the inclusion of AGs in the calculation of the best price is unlikely to substantially decrease brand-name company revenues for most drugs.[38] 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.[39] 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.

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

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[36] *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 CMS, which previously treated them as generic drugs for purposes of the rebate calculation.

[37] 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).

[38] 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.

[39] *See* Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174, 77,190 (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).

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."[40] 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."[41] 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 . . . .'"[42] 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 entry . . . .'"[43] is too broad, because "[a]s a generic firm, most of Actavis' documents will relate to whether or how to proceed with generic entry."[44] 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

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[40] PhRMA at 2. *See also* PhRMA at 7-9.

[41] PhRMA at 8.

[42] *See* Davis at 13 (quoting 71 Fed. Reg. at 16,781); *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").

[43] Actavis at 2 (quoting 71 Fed. Reg. at 16,782).

[44] Actavis at 3.

AGs and issues arising from them.[45] In addition, consistent with the FTC's previous Special Orders to the pharmaceutical industry, the "'any document'" language has been eliminated,[46] and the request has been revised to seek only high-level planning, decisional, and strategy documents.[47]

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."[48] 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; and address events that may not have occurred.[49]

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.

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[45] *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.

[46] *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 . . . .").

[47] The request has not been limited to "final" documents, however, because of the difficulty of ascertaining what is "final."

[48] PhRMA at 5.

[49] *See* PhRMA at 3, 5, 9-11.

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 . . . ."[50] PhRMA suggested, however, that the documents requested by the FTC be limited to those "maintained in the files of current officers or directors."[51] 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."[52]

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 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."[53] 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.[54] Accordingly, PhRMA requested that companies be required to produce documents "as they are maintained in the regular course of

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[50] 71 Fed. Reg. at 16,781-2.

[51] PhRMA at 12.

[52] *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).

[53] 71 Fed. Reg. at 16,781.

[54] *See* PhRMA at 13-15.

business along with a list or index identifying the person whose files the document came from."[55]

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."[56] 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.

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 January 1, 1998. GPhA and Actavis recommended that the FTC not seek documents from before January 1, 2003, because the marketing of AGs, especially during 180-day exclusivity periods, began to increase around that time.[57] 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.[58]

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

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[55] PhRMA at 14.

[56] 71 Fed. Reg. at 16,781.

[57] *See* GPhA at 4 n.5; Actavis at 2.

[58] Actavis at 1-2. *See also* GPhA at 4 (noting that agreements to market AGs did not become prevalent until late 2003).

certifications. Therefore, we are changing the date 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 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.[59] 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."[60] 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."[61] 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

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[59] 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 Fed. Reg. at 16,781). 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 Fed. Reg. at 16,781. 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.

[60] Actavis at 2-3.

[61] Davis at 12.

range of situations in which AGs are marketed.[62]

Response: The FTC agrees that the number of drugs covered by the study should be reduced by focusing on AGs[63] 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-generic drugs.[64] 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.

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[62] *See* Prasco at 2.

[63] 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.

[64] 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.

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."[65] By contrast, generic companies argued that while quantitative data are useful for 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.[66] 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."[67]

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.

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[65] 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).

[66] *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).

[67] AAI/FUSA/USPIRG at 6.

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.[68] 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 study and would be very burdensome to collect and analyze.[69]

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.[70] 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.[71]

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.

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[68] PhRMA at 17.

[69] *See* Davis at 14.

[70] *See* PhRMA at 20; Prasco at 3.

[71] Prasco at 3.

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 marketing of AGs became more common in 2003.[72] 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."[73]

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)[74] and PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (August 2005).[75] 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."[76] 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

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[72] *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").

[73] GPhA at 5.

[74] Hereinafter GENERIC DRUG REPORT.

[75] Hereinafter PBM REPORT.

[76] IMS at 2.

"manufacturers, products, and time periods."[77] 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 and would at least in part yield IMS information unrelated to the study.[78] Several pharmaceutical companies also suggested that the FTC obtain IMS data directly from IMS,[79] because "IMS Health sells its data under licenses that restrict licensees from disclosing the data to third parties."[80]

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.[81] 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."[82]

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

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[77] IMS at 2.

[78] 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).

[79] *See* Actavis at 3; Davis at 14; PhRMA at 15-16.

[80] 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.

[81] *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").

[82] GPhA at 5.

Congress, 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.[83]

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.[84] 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 certifications under the MMA.[85] Prasco also recommended that the

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[83] *See* Davis at 15-16; PhRMA at 20.

[84] *See* Lilly at 2.

[85] *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:

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.[86]

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.[87] 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;[88] the use of "product hopping" or other strategies to switch consumers from one brand-name drug to another at the onset of generic competition;[89] and the use of "reverse payments" and purportedly problematic patent settlements.[90]

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

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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).

[86] Prasco at 3.

[87] *See* PAL at 6; AAI/FUSA/USPIRG at 5; Gilbert's at 3; GPhA at 6.

[88] *See* AAI/FUSA/USPIRG at 4 (citizen petitions and declaratory judgment system); Gilbert's at 3 (citizen petitions); GPhA at 6 (citizen petitions).

[89] *See* GPhA at 6 (product hopping); Gilbert's at 3 (product switches); AAI/FUSA/USPIRG at 5 (product switches).

[90] *See* Gilbert's at 3; AAI/FUSA/USPIRG at 5; PAL at 6.

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."[91]

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 assessing] how the use of authorized generics impacts access to lower cost generic drugs, particularly for low-income individuals."[92]

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, 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.

9. Payments and Gifts to Respondents

Not applicable.

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[91] Lilly at 3. *See also* Davis at 15.

[92] AARP at 2.

10. Assurances of Confidentiality

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.[93] 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.[94]

Finally, the information presented in the study will not reveal company-specific data.[95] Rather, the Commission anticipates using anonymized data and aggregated totals, on a level sufficient to protect individual companies' confidential information. Because the Commission will be obtaining documents from a large number of companies, the planned report will be able to summarize the common features of many such documents, as well as present less common responses, without disclosing any confidential information. The Commission has used this approach before, e.g., in the PBM REPORT. Indeed, such an approach is consistent with the Commission's goal of providing a comprehensive analysis of the short- and long-term competitive effects of authorized generic drugs in the prescription drug marketplace, rather than merely anecdotal or otherwise limited information.

11. Matters of a Sensitive Nature

The collection of information does not include any questions of a sensitive nature involving matters that are commonly considered personal and private. The requests for confidential proprietary information and the FTC's ability to ensure confidentiality are discussed above.

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[93] *See* 5 U.S.C. § 552(b)(4).

[94] *See* 15 U.S.C. § 57b-2(c); 16 C.F.R. §§ 4.9 - 4.11.

[95] *See* 15 U.S.C. § 57b-2(d)(1)(B).

12. Estimated Annual Hours and Labor Cost Burden

The proposed study is a one-time endeavor that will not involve repeated responses, although brand-name companies will be required to provide a brief supplemental response identifying AGs marketed during 2007. The supplemental response will not require the production of any documents or financial data. 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.[96]

Two commenters asserted that the FTC's estimates for complying with its document requests understated the burden hours. PhRMA 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."[97] 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."[98] 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. The GENERIC DRUG REPORT, like the proposed AG study, involved document requests and financial data, and the estimated burden hours depended on the number of drugs covered. The estimated burden hours for that study ranged from 100-500 hours regarding a similar range of the number of drugs per company.[99] The estimated burden range in another study conducted pursuant to the Commission's compulsory process authority, a study of alcohol industry advertising practices, was 220-440 hours, including document production and other response preparation activities.[100] The only other PRA hour burden estimate that we are aware of that addresses the burden of producing documents is an FTC study of marketing in the entertainment industry. Although the scope of the document requests for that study was broad, covering multiple areas of marketing policies and practices, the estimated company burden

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[96] 71 Fed. Reg. 16,779, 16,783 (April 4, 2006).

[97] 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.

[98] Prasco at 2.

[99] 66 Fed. Reg. 12,512, 12,522-23 (2001). PhRMA asserts that the request for agreements in the GENERIC DRUG REPORT was narrower than the request for documents in the proposed AG study. *See* PhRMA at 4. While this may be correct, the FTC's experience with Hart-Scott Rodino notifications suggests that the burden estimate for the GENERIC DRUG REPORT may have been quite generous.

[100] 71 Fed. Reg. 62,261, 62,265-66 (2006).

specifically for responding to the document requests ranged from 225-450 hours.[101]

The FTC's experience with administering the Hart-Scott Rodino (HSR) Notification and Report Form, with an average estimated burden of 39 hours,[102] also suggests that the initial published estimate of hour burden for the AG study was reasonable.[103] Question 4(c) of that form, which requests "studies, surveys, analyses, and reports" and underlies the wording of the document requests for the AG study, is only a small part of the financial information and documents collected pursuant to a HSR Notification and Report Form. Yet, the estimated hour burden for responding to the entire form ranges from 8 to 160 hours.

Even assuming 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.[104] 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, 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,

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[101] *See* 64 Fed. Reg. 63,045, 63,047 (1999); 64 Fed. Reg. 46,392, 46,392-93 (1999). Very recently the FTC submitted for OMB review a Paperwork Reduction Act burden estimate that potentially calls for document production in conjunction with its interrogatories. Joint burden estimates for the relevant items ranged from 50 to 190 hours. *See* 72 Fed. Reg. 19,505, 19,511 (2007) (FTC Study of Food Marketing to Children and Adolescents).

[102] Notification and Report Form for Certain Mergers and Acquisitions, FTC Form C4 (rev. 6/06/06), at 1.

[103] While PhRMA asserts that HSR requests for documents "are much more targeted, involve far fewer documents, and are necessarily limited in time frame" (PhRMA at 13), the Notification and Report form requires broad information on many aspects of a company's business, yet the estimated burden hours are far fewer than for the present study.

[104] 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.

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 hours x 130 companies) + (230 x 20 companies) + (456 hours x 40 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.[105] The following table shows the estimated burden hours for different tasks for companies with different numbers of drugs covered by the study:

[105] 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.

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).

13. 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.

14. Estimate of Cost to the Federal Government

The cost of the information collection to the federal government will include the cost of staff time used to design the information requests, analyze the data collected, and produce a report. It is difficult to quantify the total cost to the Commission to complete the study because multiple factors may vary, including how quickly and completely companies respond to the

information collection requests[106] and the actual amount of time needed to complete the study. Nonetheless, staff estimates that approximately two attorney work years ($174,000 per work year, inclusive of benefits), 600 economist hours ($50,000, inclusive of benefits), and one research assistant work year ($65,000, inclusive of benefits) will be necessary to complete the study. Thus, the total remaining cost to the Commission is about $463,000. Clerical and other support services and costs of conducting the study are included in this estimate.

15. Program Changes or Adjustments

Not applicable. This is a new information collection.

16. Plans for Tabulation and Publication of Information

The information provided by the respondents will be used to prepare a report for the Commission to release publicly. The collection of the information will begin shortly after completion of the OMB review process. The projected duration of the information collection is approximately eight months. The estimated date for the completion of the report is mid-2008.

17. Display of Expiration Date for OMB Approval

Upon OMB clearance and receipt of the assigned control number, the FTC will display this number in its written document request.

18. Exceptions to Certification

Not applicable.

[106] Under the Commission's rules, the recipient of a 6(b) order (*i.e.*, an information collection request) may file a petition to quash, and the Commission may seek a court order requiring compliance.