Supporting Statement for a Paperwork Reduction Act
Submission to OMB
FTC Information Requests on the Generic Drug Competition

The Federal Trade Commission (FTC) proposes to obtain information in the form of documents and answers to interrogatories from members of the pharmaceutical industry. This statement supports a request that the Office of Management and Budget (OMB) approve the proposed collection of information.

1. Necessity for Information Collection

The proposed study will enable the Commission to provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Act.[1] The FTC has taken enforcement action against alleged anticompetitive agreements whose operation depended in part on certain Hatch-Waxman provisions.[2] The study will shed light on matters such as whether the agreements the FTC has found are isolated instances or more typical, and whether particular provisions of the Act have operated appropriately to balance the legitimate interests of pharmaceutical companies in protection of their intellectual property and the legitimate interests of generic companies in providing competition, or have instead unintentionally invited anticompetitive strategies that delay or deter market entry by generic drugs.

In light of the agreements already challenged by the FTC, and given enormous potential costs to consumers from anticompetitive activities, Representative Waxman, one of the co-authors of the Act, requested that the FTC "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S." In addition, other members of Congress, such as Senators McCain and Schumer, proposed legislation in the last Congress to amend various portions of

---

[1] The Hatch-Waxman Act provides a method by which generic drug manufacturers can obtain approval of a generic version of a branded product through an Abbreviated New Drug Application (ANDA) submitted to the Food and Drug Administration (FDA). A generic drug manufacturer must certify that the patents listed in the FDA's "Orange Book" that claim the approved drug product are invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval (a paragraph IV certification). The Act provides a 45-day window during which the patent holder may bring a patent infringement suit against the ANDA applicant. If a patent suit is initiated during this period, the Act forbids the FDA from approving the ANDA for the earlier of 30 months or until the completion of the litigation (30-month stay period). If any other generic companies file an ANDA containing a paragraph IV certification (later-filed ANDAs), the Act provides that the FDA cannot approve such ANDA until 180 days (the 180-day marketing exclusivity period) after the earlier of (1) the date of the first commercial marketing of the first applicant's generic drug, or (2) the date of a decision of a court in an action holding the branded company's patent(s) is (are) invalid or not infringed.

[2] See, e.g., In the Matter of Abbott Laboratories, Docket No. C-3945 (2000); In the Matter of Geneva Pharmaceuticals, Docket No. C-3946 (2000); In the Matter of Hoechst Marion Roussel, Inc. et. al., Docket No. 9293, Administrative Complaint (Mar. 16, 2000).

the Act, including the sections that the Commission's study would address.[3] Thus, a study based on information of the type the Commission proposes to collect will respond to Representative Waxman's request and also be relevant to consideration of various legislative proposals.

Over the next five years, brand name drugs with combined U.S. sales approaching $20 billion will go off patent.[4] This will provide an enormous opportunity for the generic industry and, conceivably, a commensurate obstacle to the brand-name pharmaceutical industry. Pharmaceutical drug manufacturers seeking to protect the sales of branded drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

2. Use of the Information

The FTC will obtain the information sought by interrogatories and document requests under Section 6(b) of the FTC Act, 15 U.S.C. § 46(b). Recipients of the special orders or information requests include name-brand pharmaceutical drug companies that have received notice of the filing of an ANDA, as defined by 21 U.S.C. § 355(j), and generic drug companies that have filed such ANDAs. The Commission has entered into an agreement with FDA to receive information about the filing of ANDAs containing paragraph IV certifications by specific product. This information will allow the Commission to tailor each special order to obtain information about specific drug products. Based on information obtained from the FDA, the Commission proposes to send special orders to approximately 30 innovator drug companies (i.e., name-brand drug manufacturers) and 70 generic drug companies to examine their use of agreements and other strategies that may affect generic drug competition. The Commission anticipates that approximately 70 percent of both innovator companies and generic companies will have no more than three drug products relevant to the information requests.

The Commission plans to compile the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions of the Hatch-Waxman Act have influenced the development of generic drug competition. For example, the Commission anticipates that the study will analyze how often the 180-day marketing exclusivity provision has been used, how it has been triggered (by commercial marketing or court orders), the frequency with which innovator companies initiate patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. The Commission will use the agreements provided, along with the underlying documents related to the reasons for executing the agreement, to provide a discussion of whether the agreements between innovator and generic companies (or between generic companies) may have operated to delay generic drug competition. In addition, the study will provide information

---

[3] S. 3051, 106th Cong. (2000).

[4] National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection" (August 2000) at 3.

about innovator companies' patent listings in the Orange Book, and how frequently generic companies challenge these listings. The study also will provide illustration of innovator company use of citizen petitions relating to generic versions of their brand-name drug products. Finally, the study will examine whether the size of a drug product's sales influences the likelihood of the use of strategies that delay generic competition.

The documents and information collected also may provide a basis for initiating a law enforcement investigation, but 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 indicates unfair methods of competition. See FTC Act Section 5, 15 U.S.C. § 45.

3. Information Technology

Improved information technology may assist in gathering and producing this information. Where possible, the FTC will allow respondent to use electronic or automated collection techniques. 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 studies, data, hearing transcripts, news articles, and information found through contacts with industry trade associations, consumer groups, governmental agencies, and academic researchers. As previously stated, the Commission also has entered into an agreement with FDA to receive information about the filing of ANDAs containing paragraph IV certifications by specific product. This information will allow the Commission to tailor each company's request to specific drug products.

The Congressional Budget Office (CBO) has produced a study examining the extent to which competition from generic drugs has increased since the passage of Hatch-Waxman Act and analyzing how that competition has affected the returns from developing a drug.[5] The CBO study does not, however, provide information on whether the 180-day marketing exclusivity and 30-month stay provisions of the Act have encouraged generic competition or facilitated the use of anticompetitive strategies. Thus, the CBO study does not substitute for the proposed one.

The FTC will not require submitters to provide any documents that have been previously submitted to the Commission pursuant to the Premerger Notification Rules (16 C.F.R. Parts 801-803

[5] Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (CBO study) (July 1998).

(2000)) and Section 7A of the Clayton Act (15 U.S.C. § 18a) or Sections 6, 9, 13, and 20 of the Federal Trade Commission Act (15 U.S.C. §§ 46, 49, 53, and 57b-1), although responding companies will be required to identify any such documents.

5. Efforts to Minimize Small Organization Burden

The information collection request is not likely to impose an undue burden on small entities, such as small generic drug companies. To the extent that a respondent is a small entity, it is likely that the specific list of drug products contained in the information collection request will be limited in number. 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 generic drug companies with the largest number of drug products for which information will be sought are not small businesses. Moreover, as previously mentioned, approximately 70 percent of innovator companies and generic companies will be asked to provide information relating to three or fewer specific drug products, thereby limiting their burden. Finally, Commission staff will answer any questions a respondent may have relating to the scope or meaning of anything required by the information collection request, and will consider possible modifications thereto to reduce burdens on small entities.

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 generic drug competition has developed in light of certain provisions in the Hatch-Waxman Act that govern entry of generic drug products. The Commission believes that the proposed study will enable it to provide a more complete picture of how generic drug competition is developing under the Hatch-Waxman Act and to ensure that consumers obtain the full benefits of generic drug competition as envisioned by the Act. The documents and information provided also may provide the basis for initiating a law enforcement investigation against particular anticompetitive practices. The Commission has endeavored to reduce associated paperwork burden as much as possible.

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

As required by 5 C.F.R.§ 1320.8(d), the FTC published a notice seeking public comment on the proposed collections of information. See 65 Fed. Reg. 61,334 (Oct. 17, 2000). A copy of the FTC's publication is attached as Appendix A.

The FTC received 11 comments on the proposed information collection requests.[6] Eight of the comments (BCBSA, GM, HIAA, Keats, Microbix, NACDS, Pharmacy Defense, and RxHealth) endorsed the proposed study, indicating, for example, that the "proposed requests for information are necessary to the FTC's function as the primary governmental agency charged with protecting consumers from anticompetitive practices." HIAA Comment at 1. Four of the commenters endorsing the study (GM, Keats, NACDS, and Pharmacy Fund) also suggested that the Commission broaden its proposed study to include investigation of various practices of pharmaceutical companies that may have an effect on generic drug competition.

No generic drug company opposed the Commission's proposed study or questioned its practical use, but Geneva recommended that the Commission narrow the proposed study "in ways that should not compromise the Commission's objectives." Geneva Comment at 1.

PhRMA and CRE asserted that the Commission had not yet complied with the requirements of the Paperwork Reduction Act (PRA); PhRMA also included suggestions for narrowing the study if undertaken.

As discussed below, the Commission incorporates several of the suggestions to narrow the study to reduce burden and to avoid collecting documents that the Commission did not intend to collect. However, other proposals to narrow the proposed study would unnecessarily limit the study's usefulness. Likewise, the Commission has not followed the suggestions to broaden the proposed study to investigate the pricing and distribution practices of pharmaceutical companies, because the magnitude of such an investigation is beyond the proposed study's scope and the resources available to complete it in a timely manner. The following discussion of issues raised by the comments is organized into three sections: (1) the practical utility of the proposed study and why it is necessary for the proper

---

[6] BlueCross BlueShield Association (BCBSA) (federation of independent Blue Cross and Blue Shield health insurance plans), The Center for Regulatory Effectiveness (CRE) (self-described independent organization to provide Congress with analyses of agency regulations), Geneva Pharmaceuticals (Geneva) (generic drug manufacturer), General Motors Corporation (GM) (automaker), Health Insurance Association of America (HIAA) (trade association representing the private health care system), George Keats (Keats) (private citizen), Microbix Biosystems, Inc. (Microbix) (pharmaceutical company), National Association of Chain Drug Stores (NACDS) (trade association representing chain drug stores), Pharmaceutical Research and Manufacturers of America (PhRMA) (trade association representing research-based pharmaceutical and biotechnology companies), Pharmacy Defense Fund (Pharmacy Fund) (advocacy organization on behalf of pharmacists), and RxHealth Value (RxHealth) (a coalition representing consumers, labor unions, provider organizations, health plans and insurers, business health groups, large employers, and pharmacy benefit management organizations).

performance of the FTC's functions; (2) suggestions to narrow the focus of the study; and (3) suggestions to broaden the focus of the study. The comments about the FTC's compliance with the PRA are addressed in various other sections of this Supporting Statement and are not repeated here.

1. 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 more complete picture of how generic competition is developing in light of certain provisions of the Act that govern entry of generic drug products.

Comments: Most comments stated that the proposed study will have practical utility. See, e.g., GM Comment at 1; HIAA Comment at 1; and NACDS Comment at 1. CRE and PhRMA, however, asserted that the proposed study will have no practical utility and that the Commission has not articulated how the information collected would be used to meet the Commission's stated goals. CRE Comment at 4-7; PhRMA Comment at 1-3, 5. In particular, CRE stated that significant portions of FDA's implementing regulations for relevant sections of the Act were invalidated by a series of court decisions to which FDA has responded by issuing interim rules and initiating a rulemaking to develop new governing regulations that have not yet issued. CRE further explained that an FTC staff comment in that FDA rulemaking proceeding states "that such [proposed] revisions may well assuage FTC concerns." Accordingly, CRE asserted that the information the FTC proposes to collect has no practical utility at this time and that the FTC should wait until FDA issues final regulations before determining whether to undertake the proposed study. CRE Comment at 7. Likewise, PhRMA asserted that the proposed study is not necessary because: (1) the FTC's past law enforcement actions regarding agreements entered into between innovator and generic companies "have already sent a strong message to the industry of the FTC's concerns" and private litigation stimulated by the FTC's investigations has further reinforced its message; (2) the FTC staff has indicated in a comment to FDA that FDA's proposed revisions "may remedy the delayed generic competition that has resulted from certain types of agreements between generic and innovator companies" and that the proposed study is unlikely to add new insight; and (3) the FTC is likely to become aware of agreements between innovator and generic companies because these agreements are usually publicized given that they often exert a substantial impact on the participants' businesses, and thus the study is unlikely to uncover new agreements of concern. PhRMA Comment at 2.

Response: To the extent that the necessity of the study and use of the information sought are addressed under Items 1 and 2 of this Supporting Statement, those subjects are not repeated here. Additional points supporting the study are detailed below.

The purpose of the proposed study is to examine the extent to which the 180-day marketing exclusivity and 30-month stay provisions of the Act have encouraged generic competition or facilitated the use of anticompetitive strategies. The information requested concerns the use of agreements between innovator and generic drug companies relating to these two provisions, the business reasons for entering these agreements, and other data regarding how innovator and generic drug companies have operated in light of the 180-day marketing exclusivity and 30-month stay provisions of the Act. For example, the Commission anticipates that the study will analyze matters such as how often the 180-day marketing exclusivity provision has been used, how it has been triggered (by commercial marketing or court orders), the frequency with which innovator companies initiate patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. In addition, the study will provide factual evidence regarding innovator companies' patent listings in the Orange Book, and how frequently challenges are made to patent listings for drug products as to which generic companies have filed ANDAs containing a paragraph IV certification under the Hatch-Waxman Act. Finally, the information relating to company sales will provide evidence of whether the magnitude of revenues associated with particular products correlates with possible strategies relevant to the 180-day marketing exclusivity and the 30-month stay provisions.

HIAA suggested that "the information the FTC proposes to collect will have significant practical utility in determining whether drug manufacturers are engaging in practices that impede generic competition and the extent to which consumers are harmed by such behavior." HIAA Comment at 1. RxHealth suggested that "there is ample evidence of use of Hatch-Waxman by branded manufacturers to prevent or delay timely entrance of generic competitors to the market." RxHealth Comment at 1. Pharmacy Fund strongly supported the proposed study "for it portends an opportunity for the major drug innovators, the generic industry, and consumers to better understand and explain behaviors that are now seen as murky or unfair." Pharmacy Fund Comment at 1. The NACDS stated that the "document collection is necessary because the practices are anticompetitive." NACDS Comment at 1. And "GM believes that the FTC can and should examine the practices and agreements that extend monopoly positions and restrict trade to determine whether there has been any violation of the antitrust laws." GM Comment at 1. As BCBSA noted in its comment, the study has additional utility in light of the top-selling brand name drugs (e.g., Claritin, Pravachol, Prilosec, Prozac, Vasotec, and Zocor) that will go off patent over the next five years. BCBSA Comment at 1. Thus, regardless whether past Commission enforcement activity has "sent a strong message to the industry," as PhRMA suggested, the study will still be responsive to Representative Waxman's request and also relevant to other legislative proposals.[7]

GM and BCBSA both described the increasing costs of prescription drugs and the importance of generic drug competition to reduce total health care expenses without adversely affecting the level of care provided. For example, GM stated that its total drug expenditure for calendar year 2000 will

[7] See note 3 and accompanying text.

exceed $1.2 billion and that brand-name drugs account for 90 percent of its total drug spending, although its current utilization rate for generic drugs is 37 percent. Moreover, for each one percent increase in the use of generic drugs, GM can save $3 million per year. Id. at 2.

The proposed study falls squarely within the FTC's fact-finding authority under Section 6 of the Federal Trade Commission Act. See 15 U.S.C. § 46(a). The Commission's power to investigate and report on marketplace developments is part of the FTC's original mandate and has been the basis for important studies in the past.[8] In the pharmaceutical area, the Commission has used its Section 6 authority to investigate the issue of advertising and promotion of prescription drugs.[9]

The FDA's current rulemaking proceeding to revise the regulations implementing the Act does not undermine the FTC's proposed study. The proposed study seeks to examine whether the 180-day marketing exclusivity and 30-month stay provisions of the Act have encouraged generic competition or facilitated the use of anticompetitive strategies.[10] The FDA's implementing regulations, regardless of when they are issued, cannot change the Act's statutory language, and it is the effect of these statutory provisions on generic competition that is the focus of the proposed study. Moreover, FDA's final regulations will be prospective in effect, and FDA has provided no indication as to when they will be completed.[11] In June 1998, the FDA published industry guidance on FDA's current approach to the

---

[8] For example, a study of the radio broadcasting industry influenced passage of the Radio Act of 1927 (a predecessor to the Communications Act of 1934), while the FTC's disclosure of securities issue abuses played a role in heightening Congress' recognition of the need for securities industry regulation and led to the Securities Act of 1933. See also FTC v. Rockefeller, 591 F.2d 182 (2d Cir. 1979); FTC Line of Business Report Litigation, 595 F.2d 685 (D.C. Cir.), cert. denied, 439 U.S. 958 (1978).

[9] Federal Trade Commission, Bureau of Economics, Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets (1977). And, more recently, the Commission continues to use its Section 6 authority to examine cigarette labeling issues. Federal Trade Commission Report to Congress for 1998 Pursuant to the Federal Cigarette Labeling and Advertising Act (2000) <http://www.ftc.gov/os/2000/06/index.htm#27>.

[10] The benefits of generic drug competition for consumers have been examined extensively. See, e.g., Staff Report, Bureau of Economics of the Federal Trade Commission, The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change (Mar. 1999) at 18; CBO study, note 5.

[11] PhRMA has argued that FDA's proposal, which the FTC staff suggested may address several of FDA's concerns about delayed generic competition, is neither authorized by the Act nor consistent with the policy objective of the 180-day marketing exclusivity provision. See Comments of PhRMA, In re 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, Docket No. 85N-0214 (Aug. 6, 1999) at 5-6. If the FDA were to adopt its proposed regulations, they could be challenged in court, with a possible delay in their implementation.

180-day marketing exclusivity issue,[12] and it published an interim rule and "has regulated directly from the statute when making exclusivity decisions on a case-by-case basis."[13] In addition, the information collected also will likely shed light on whether FDA's proposed regulations are sufficient to remedy any delayed generic competition that results from certain types of agreements.[14]

Contrary to PhRMA's suggestion, it is unlikely that the Commission would be able to uncover all potentially anticompetitive agreements without undertaking the proposed study. See NACDS Comment at 2 ("The existence of an anticompetitive agreement is rarely if ever publicized by the manufacturers."). The Commission's enforcement experience in this area is that, although it has public notice of an agreement's existence (e.g., notice of a court settlement), the Commission cannot learn of the specific terms of an agreement until it opens an investigation of the matter.

2. Suggestions to Narrow the Focus of the Proposed Study

The discussion of this section is separated into three subsections below. Subsection (a) discusses the suggestions to revise the language of Request 1 for both innovator and generic companies. Request 1 seeks agreements relating to ANDAs and documents supporting the reasons for entering into these agreements. Subsection (b) discusses suggestions to revise the three remaining questions, which are asked of only innovator companies (Requests 2-4 for innovator companies), and subsection (c) discusses suggestions for changes to the remaining four questions for generic companies (Requests 2-5 for generic companies).

a. Information Request for Innovator and Generic Companies to Submit Agreements and Supporting Documents

Current Request: Request 1 for both innovator and generic companies requires them to produce all agreements entered into since January 1, 1991 between the company and any other person

---

[12] FDA, Guidance for Industry, 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (June 1998).

[13] FDA, 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42874 (Aug. 6, 1999).

[14] The FDA recently revised its interpretation of the conduct sufficient to constitute "commercial marketing" that triggers the 180-day marketing exclusivity right. See Letter of Janet Woodcock, Director, FDA Center for Drug Evaluation and Research, to Deborah A. Jaskot, Docket No. 00P-1446/CP1 (Feb. 6, 2001). This action reflects FDA's concern that the 180-day marketing exclusivity right not be used to impede generic competition.

relating to an ANDA for drug products specified for each respondent company.[15] The request lists as examples of such agreements: (a) patent litigation settlements (full or partial); (b) agreements related to the filing (or non-filing) of an ANDA by any applicant (or potential applicant); (c) licensing agreements between the company and persons that have filed an ANDA; and (d) agreements related to any acquisition, divestiture, joint venture, alliance, license or merger by the company of any business involving the research, development, manufacture or sale of any drug product that is the subject of an ANDA. The company is not required to submit purchase orders for base active materials, equipment and facility contracts, and employment contracts. The second part of the request requires the companies to produce any documents prepared by or for any officer or director of the company that would provide reasons for why the agreement was executed.

Comments on Date Range: Geneva suggested that the Commission modify the cutoff date to January 1, 1995, except for still-active agreements between innovator and generic companies that prohibit the generic company from launching a generic version of the innovator's patented product in return for consideration.

Response: We agree with Geneva's suggestion to modify the date range of agreements studied and will request only agreements executed after December 31, 1994. We also agree to implement a modified version of the backstop that Geneva suggested and request that still-active agreements entered into before such date be produced. This change will reduce the burden on the responding companies by reducing the time period for which they must produce agreements by four years (1991 through 1994), while still enabling the Commission to provide a more complete picture of how generic drug competition has developed.

Comments on Scope of Agreements Collected: PhRMA recommended that, if the proposed study is undertaken, the Commission collect only "agreements between an innovator and a person that has filed an ANDA or may file an ANDA and in which the ANDA filer or potential ANDA filer commits to refrain from or delay its ANDA filing or the commercial marketing of a generic product in return for consideration from the innovator." PhRMA Comment at 5. In addition, PhRMA stated its views that the information collection request appears to cover three types of agreements that could not have been intended to delay the introduction of a competing generic product: (1) licensing agreements and other agreements between innovators and generic manufacturers that relate to already marketed generic drug products; (2) agreements entered into before the innovator became aware that the generic manufacturer had filed or intended to file an ANDA; and (3) merger, acquisition, and licensing agreements between two innovator companies if one of them manufactures a drug product that is the subject of an ANDA. PhRMA Comment at 4. Geneva also provided examples of agreements that would be included in the Commission's information request but are not within the Commission's

[15] The Commission has entered into an agreement with FDA to receive information about the filing of ANDAs containing paragraph IV certifications by specific product. This information will allow the Commission to tailor each company's request to specific drug products.

perceived concern. To remedy this concern, "Geneva suggests that the request be limited to agreements with innovator companies relating to ANDAs, where the innovator company holds the NDA [new drug application underlying the branded drug product] corresponding to the ANDA that is subject of the agreement." Geneva Comment at 2. Geneva also suggested that the Commission clarify that it will not seek any agreements or documents that the Commission may already have as a result of any law enforcement matter.

Response: PhRMA has suggested that the Commission request only agreements whose terms mirror the terms in the agreement that Commission alleged to be anticompetitive in its enforcement action against Abbott and Geneva.[16] If the Commission were to accept PhRMA's suggestion to limit its investigation to agreements with those specific terms, it would lessen the practical utility of the proposed study. One objective of the proposed study is to determine whether innovator companies and generic drug companies have entered into various types of agreements that have affected the development of generic drug competition. The request, as currently drafted, may uncover other, somewhat different examples of agreements that have affected the development of generic competition, but that do not contain the terms specified by PhRMA. As NACDS explained in its comment, the "FTC needs to collect relevant documents to discover new examples of [possibly anticompetitive agreements]." NACDS Comment at 2.

On the other hand, the Commission's experience also has suggested that there may be circumstances where agreements between innovator and generic drug companies are procompetitive. The request, as currently drafted, may uncover such agreements as well. These agreements also are likely to assist the Commission's investigation of how generic competition has developed in light of the Act. Thus, the proposed study may identify procompetitive rationales in support of other agreements that have somewhat different terms, thereby illuminating benign reasons for conduct that some currently see as "murky or unfair." Pharmacy Fund Comment at 1.

To limit the study as PhRMA suggested would severely limit the Commission's ability to examine the use of agreements in this industry. One question is whether anticompetitive agreements of the type challenged by the FTC are isolated instances or examples of typical practices. By asking for a range of agreements over a six-year period, the Commission believes it will be able to provide a more complete picture of agreements related to generic drug competition and Hatch-Waxman Act provisions. The much more limited request that PhRMA proposed would likely yield, at best, only anecdotal evidence of how certain types of agreements between innovator and generic companies affect generic drug competition.

The Commission agrees, nevertheless, with Geneva's and PhRMA's assertion that the language specifying the agreements to be produced can be narrowed in certain respects without compromising

---

[16] See In the Matter of Abbott Laboratories, Docket No. C-3945 (2000); In the Matter of Geneva Pharmaceuticals, Docket No. C-3946 (2000).

the Commission's objectives. The Commission does not intend the request to cover agreements not likely to further the study's objectives. Accordingly, the language of Request 1 for both innovator and generic companies has been modified to make each request symmetrical and more narrowly focused. The Commission has incorporated PhRMA's suggestion to exclude agreements entered into between innovator companies and generic manufacturers that relate to already marketed generic drug products. In addition, it has incorporated PhRMA's and Geneva's suggestions concerning duplication, to exclude from the request documents that have been submitted previously to the Commission pursuant to the Premerger Notification Rules (16 C.F.R. Parts 801-803 (2000)) and Section 7A of the Clayton Act (15 U.S.C. § 18a) or Sections 6, 9, 13, and 20 of the Federal Trade Commission Act (15 U.S.C. §§ 46, 49, 53, and 57b-1), although responding companies will be required to identify any such documents.

PhRMA's suggestion to exclude agreements entered into before the innovator became aware that the generic manufacturer had filed or intended to file an ANDA creates uncertainty as to how companies would respond to the request. Agency experience suggests it would be difficult to provide objective guidance to define when an innovator company "became aware" that a generic company intended to file an ANDA. Accordingly, and in light of the Commission's actions to narrow the request in other significant respects, the Commission declines to implement this suggestion.

In addition, the Commission has not followed Geneva's suggestion to exclude licensing arrangements or co-development agreements between generic manufacturers. The Commission's law enforcement investigations indicate that agreements between generic companies also may affect the degree of generic competition that emerges. To exclude such agreements could eliminate a substantial number of agreements and documents that may help provide a more complete picture of whether agreements among generic companies may have delayed the consumer benefits of full generic competition.

Comments on Documents Containing Reasons for Executing Agreements: PhRMA further suggested that the second half of Request 1, which requires documents relating to the reasons for making the identified agreements, is "extremely ambiguous" and fraught with potential technical difficulties as to which documents a company would be required to produce.

Response: The additional documents called for in the second half of Request 1 include only those important enough to be prepared for or by an officer or director of the company and that evaluate or analyze the company's reasons for entering into agreements identified in response to Request 1. These documents will help ensure that the Commission has a full picture of the reasons for the agreements, including procompetitive reasons. This language is routinely used to request documents in connection with premerger notification filings pursuant to the Premerger Notification Rules (16 C.F.R. Parts 801-803 (2000)) and Section 7A of the Clayton Act (15 U.S.C. § 18a). Responding companies generally recognize and understand the language. Limiting the pre-merger request to documents

prepared by or for an officer or director of a company usually results in the production of a small number of documents (in most cases fewer than five).

The revised text of Request 1 for both innovator and generic companies (as well as the remaining Requests) is attached as Appendix B. The Commission also has made minor changes to the Requests to clarify the language of each Request as applicable.

b. Remaining Information Requests for Innovator Companies:

The Commission has proposed three additional information collection requests of innovator companies. Request 2 requires a company to produce information about patents listed in the Orange Book for specified drug products. Request 3 requires a company to produce information about litigation to which it is a party and that relates to an ANDA containing a paragraph IV certification. Request 4 requires a company to produce sales data regarding each specified drug product.

Comments: PhRMA has suggested that the information sought by Requests 2 through 4 is freely available to the FTC, at least once the agency receives any agreements called for by Request 1. In addition, it suggested that these requests are "both unnecessary and ambiguous." Accordingly, it suggested that the FTC use a two-stage process -- first, collect agreements, and then, if necessary, collect additional information -- to proceed with the proposed study.

Response: For the Commission to use a two-stage process, as PhRMA suggested, to collect the documents and information sought by Requests 2 through 4 (i.e., patent listings in the Orange Book, patent litigation information, and sales information) would unnecessarily delay the study and likely prevent the Commission from producing it in a timely manner. The information from the study is most likely to be of relevance as the 107th Congress considers possible changes to the Hatch-Waxman Act. In its comment, HIAA also suggested that a study would be timely given the central role that pharmaceuticals play in medical cost inflation, with spending for prescription drugs far outpacing all other major categories of health expenditures. HIAA Comment at 2. In addition, a two-stage process could unduly burden companies by requiring them to search the same files twice -- once in response to the current requests, and at a later date to comply with a second round of information requests.

The information requested in Requests 2 through 4 is necessary to show how and when generic competition has begun for various drug products. Request 2 seeks information about patents listed in the Orange Book for specified drug products. GM, NACDS, and Microbix highlighted the need to examine the practice of listing patents in the Orange Book in ways that could potentially delay generic drug entry. GM Comment at 2, Microbix Comment at 2, NACDS Comment at 1-2. For example, this information is crucial to determine how often and when innovator companies have filed new patents after the drug product has been approved and thereby triggered the 30-month stay provision. Such listings can affect when generic competition starts. Because patent listing dates are not provided in the

Orange Book, the request seeks the listing date of patents in the Orange Book for specified drug products.

Request 3 seeks basic information regarding patent lawsuits initiated by the innovator company related to a generic drug product for which the innovator company holds the rights to the corresponding NDA. This information is useful to examine how the 180-day marketing exclusivity period is triggered and how often a court decision is used to resolve patent disputes. The Commission has modified the language of the request to ensure that the companies do not produce non-responsive court documents. Pharmacy Fund has urged the Commission to obtain this information and related court documents because courts usually grant the innovator companies protective orders that shield the public (and the FTC) from knowing the terms by which lawsuits are settled. Pharmacy Fund Comment at 2. Thus, this information often cannot be obtained from the court directly, and would thus have to be collected from the companies themselves.

Finally, Request 4 seeks information regarding a company's annual sales in units and dollars for each specified drug product. This information is necessary to evaluate whether companies' actions may be correlated to the market value of a particular drug product. This information should be readily available at corporate headquarters.

c. Remaining Information Request for Generic Companies

The Commission received several comments from Geneva on three of the four proposed information collection requests of generic companies.

Comments: Geneva requested that Request 2 -- which seeks, among other things, a description of how patent litigation expenses are or have been distributed among the parties to the litigation -- be stricken, or that a further explanation be given as to how the requested information will be useful and as to what procedures will be used to keep information received confidential. Geneva also suggested that Request 3, which seeks information about generic drug commercial marketing, be narrowed or made less burdensome. Finally, Geneva suggested that Request 5, which seeks sales data for specified drug products, be amended to request sales data only for those drug products for which the company has filed an ANDA containing a paragraph IV certification and that actually resulted in patent litigation between the generic company and the innovator.

Response: Request 2 for generic companies seeks information relating to how patent litigation expenses are or have been distributed among the generic companies party to the litigation. Although there is little legislative history, it is commonly understood that the 180-day marketing exclusivity period was implemented to reward the first-filed paragraph IV ANDA applicant for bearing litigation expenses to successfully challenge the branded company's patents and also to prevent free-riding by later-filed paragraph IV ANDA applicants. The information to be provided for Request 2 will help determine whether the provision has operated to achieve that goal. In many cases, the innovator

company has sued not only the first-filed ANDA applicant for patent infringement, but also later-filed applicants, and courts have consolidated these cases so that generic companies are often joint defendants. As described below in more detail, all information and documents submitted pursuant to the information request will be kept confidential under the FTC's Rules of Practice.

Requests 3 and 5 seek information regarding the commercial marketing of drug products for which the generic company has submitted an ANDA containing a paragraph IV certification. The Commission believes it is unnecessary to limit the data collection further as suggested by Geneva (only to drug products subject to Paragraph IV certifications that actually resulted in patent litigation between the generic company and the innovator) because each information collection request will be tailored by drug product for each company. Based on initial information obtained from the FDA, as previously noted, approximately 70 percent of the generic companies will be asked to provide information relating to three or fewer specific drug products. Thus, it should be relatively easy for the company to identify when it received regulatory approval and what its sales were for each individual drug product for the specified number of years.

3. Suggestions to Broaden the Scope of the Proposed Study

Comments: GM, Keats, NACDS and Pharmacy Fund suggested ways in which the Commission should broaden the study's focus. NACDS suggested that the Commission "investigate the extent to which brand name drug manufacturers file baseless citizen petitions with the Food and Drug Administration that challenge the FDA's approval of a generic drug product." NACDS, along with GM, Keats, and Pharmacy Fund, also suggested that the Commission examine pricing strategies of drug manufacturers. NACDS Comment at 2. GM specifically suggested that the Commission investigate pricing practices of pharmaceutical companies for U.S. consumers compared to Europe or Japan and study the need for consumer education in this area (GM Comment at 2); Keats suggested that the Commission study how manufacturers influence the distribution of their drug products (Keats Comment at 1); and Pharmacy Fund suggested the Commission seek information regarding "the marketing conditions that preclude competitive market pricing by the innovator company." Pharmacy Fund at 2. Pharmacy Fund also suggested that the Commission examine the practices of a specific company and examine whether innovator companies engage in direct-to-consumer disparagement of generic drug products. Id.

Response: Commission staff has commented to the FDA on the FDA's proposed rules governing citizen petitions suggesting changes that might reduce the potential for regulatory abuse.[17]

[17] Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, FDA Docket No. 99N-2497 (Mar. 2, 2000) ("staff comment").

Staff explained that there is potential for anticompetitive abuse of nearly any regulatory process.[18] To delay competition may be a lucrative strategy for an incumbent, especially in an industry where entry is regulated, such as pharmaceuticals. Improper petitioning may be appealing in part because it can be used against any size firm, regardless of relative resources of the parties. The cost of filing an improper citizen petition may be trivial compared to the value of securing a delay of a year or more (or possibly as little as a month's delay for a blockbuster drug) in a rival's entry into a lucrative market.[19]

Participation in the regulatory process, however, is often protected from antitrust scrutiny by the Noerr-Pennington doctrine.[20] In its simplest terms, the Noerr-Pennington doctrine shields private parties from antitrust liability when they engage in concerted but genuine efforts to influence governmental action, even though the conduct is undertaken with an anticompetitive intent and purpose. If regulatory intervention (or a series of interventions) is used to impede competition, however, antitrust concerns may be raised if not shielded by Noerr-Pennington.[21]

One of the recommendations in the staff comment was that the FDA consider requiring notification of whether the citizen petitioner has received, or will receive, consideration for filing the citizen petition and identification of the party furnishing the consideration.[22] This information may be important in evaluating the likely competitive effect of the petition.[23] In light of this potential, the Commission will seek limited, identifying information regarding the filing of citizen petitions by innovator companies for specified drug products. The information will be used to determine how frequently innovator companies have filed, or contributed to the filing of, citizen petitions with the FDA for specified drug products. The information will not be used to review the merits of the petitions or to evaluate FDA's handling of the petitions.

---

[18] Accord, Robert H. Bork, The Antitrust Paradox 347 (1978) ("The modern profusion of [. . .] governmental authorities offers almost limitless possibilities for abuse.").

[19] Id. at 348.

[20] Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc. 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965).

[21] Professional Real Estate Investors, Inc. v. Columbia Pictures Indus. Inc., 508 U.S. 49 (1993); see also Bork, supra n. 18, at 354.

[22] The Commission recently imposed a similar condition in conjunction with its approval of the Coastal Corp. and El Paso Energy Corp. merger. The Commission required the merged entity to disclose publicly whenever it undertook regulatory action on its own or through the funding of third parties to oppose the regulatory approval of a natural gas pipeline that would compete with the merged company. FTC Press Release, "FTC Clears Merger of El Paso Energy and Coastal Corp." (Jan. 29, 2001) <http://www.ftc.gov/opa/2001/01/elpasocoastal.htm>.

[23] The Senate bill referenced in note 3 also included a provision relating to the use of citizen petitions and their potential for delaying generic drug competition.

An investigation of pricing practices of pharmaceutical companies is beyond the scope of the study. Likewise, GM's suggestion that the Commission use the proposed study to address the need for consumer education about generic drugs, although worthwhile, is also beyond the scope of the proposed study. The Commission recognizes the importance of pricing practices and their effect on generic drug competition. The scope of the study, however, is limited to the use of agreements and other non-price strategies that are intended to delay generic drug competition. The Commission does not have the resources at this time to adequately investigate pharmaceutical pricing issues.

The Commission study is not designed to target any specific companies. Pharmacy Fund's request that the Commission do so lies outside ths scope of the study. See discussion of item #2 of this Supporting Statement.

Finally, the Commission declines to broaden the study to examine direct-to-consumer disparagement of generic drug products. It is beyond the scope of the resources allocated for this study to fully examine the issues surrounding possible direct-to-consumer disparagement.

9. Payments or Gifts to Respondents

Not applicable.

10. & 11. Assurances of Confidentiality/Matters of a Sensitive Nature

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 C.F.R. §§ 4.9 - 4.11. Finally, the information presented in the study will not reveal company-specific data. See 15 U.S.C. § 57b-2(d)(1)(B). Rather, the Commission anticipates using aggregated totals, on a level sufficient to protect individual companies' confidential information, to provide a factual summary of how the provisions of the Act have operated for the specified period.

12. Estimated Annual Hours Burden

FTC staff will ask members of the pharmaceutical industry to answer several written questions about specific drug products and to produce certain documents related to the answers provided. We believe that the burden estimates are reasonable given the refinements to the wording of Request 1 for innovator companies and generic drug companies (request seeking agreements and documents explaining the reasons for executing the agreements) to delete four years from the time period and to ensure that the question's language does not cover agreements that the Commission did not intend to be produced. Staff has increased the low-end estimate given the additional question now asked of innovator companies concerning citizen petitions.

The burden estimates were based in the first instance on experience in administering the Antitrust Improvements Act Notification and Report Form (Form) that implements the notification requirements of the Premerger Notification Rules and Section 7A of the Clayton Act. Request 1 for both innovator and generic companies is comparable to the information required for question 4(c) of the Form. Based on historical experience, respondents require an average of 39 hours to complete the Form.[24] This average formed the basis for the estimated hours needed to respond to Request 1,[25] premised on the above-stated assumption that the Commission will ask most companies for information on no more than three drug products. Commission staff allocated 15 hours to respond to the additionally requested information based on its knowledge of how the requested information is generally maintained by companies that respond to such Commission requests. Thus, an additional 45 hours (3 questions x 15 hours each) initially were allocated for innovator company questions for a total of 84 hours (39 hours + 45 hours) and an additional 60 hours (4 questions x 15 hours each) for generic companies for a total of 99 hours (39 hours + 60 hours).

Now that the Commission has added a question for innovator companies concerning citizen petitions, which it also estimates will require approximately 15 hours to answer, the lower-end estimate is approximately 100 hours for innovator companies as well as generic companies. The revised, high-end of the estimated range (500 hours) recognizes that some companies (approximately 30 percent of innovator companies and generic companies) will have to produce information for more than three drug products, with fewer than five percent of the companies having to produce information on more than 10 drug products. At the same time, the upper-end estimate, though based on this higher volume, also recognizes inherent economies of scale for the process of organizing, identifying, and retrieving information responsive to these requests.

---

[24] Federal Trade Commission, Submission for OMB Review, 64 Fed. Reg. 36877 (July 8, 1999); 66 Fed. Reg. 8679, 8705 (February 1, 2001).

[25] This is a conservative estimate in that the Form requires more data to be described and produced than merely the information sought by Request 1. Moreover, the estimate does not factor in that some companies may not have entered into any of the agreements described in Request 1.

The estimated burden of answering the questions and producing documents per respondent on a functional basis breaks down as follows:

Organize document and information retrieval	20 - 50 hours
Identify requested information	20 - 200 hours
Retrieve responsive information	25 - 100 hours
Copy requested information	10 - 50 hours
Prepare response	25 - 100 hours
	100 - 500 hours

The cumulative hours burden to produce documents sought and prepare the response will be between 9,000 hours (100 hours x 90 companies) and 45,000 hours (500 hours x 90 companies).

Associated Labor Cost:

It is not possible to calculate precisely the labor costs associated with answering the questions and producing the documents requested, as responses will entail participation by management and/or support staff at various compensation levels among many different companies. Individuals among some or all of those labor categories may be involved in the information collection process. Based on Geneva's comments, staff has increased the dollar figure per hour to reflect the use of outside legal counsel along with mid-management personnel for handling most (an assumed 90 percent) of the tasks involved to gather and produce the responsive information. For such labor costs, we estimate an average hourly wage of $250/hour. In addition, staff estimates an average hourly wage of $10 for the labor of clerical employees who will copy the responsive materials. Thus, the labor costs per company should range between $22,600 [(90 hours x $250/hour) + (10 hours x $10/hour)] and $113,000 [(450 hours x $250/hour) + (50 hours x $10/hour)], with approximately 70 of the 100 companies (70 percent x 70 generic companies plus 70 percent x 30 innovator companies) averaging approximately $22,600 to respond to information requests. Assuming the remaining 30 companies average approximately $67,800 each in labor costs (the mean within the estimated range), total estimated labor cost is $3,616,000 ((70 x $22,600) + (30 x $67,800)). By comparison, for example, the Commission alleged that Abbott paid Geneva a sum of $4.5 million per month to keep the generic version of Hytrin off the market.[26] Thus, the Commission believes that the estimated cost is reasonable in light of the size of the markets involved, the potential consumer harm, and Congressional interest in the area.

Geneva estimates that the burden will be "in excess of $300,000" to respond to the information collection request as proposed. Geneva Comment at 2. The Commission believes Geneva's estimate is based on a misunderstanding of the scope of the information collection request. First, the Commission has clarified the language of Request 1 to exclude agreements not intended to be covered by the request. Second, the Commission has significantly shortened the time period (by four years) for

[26] See note 2.

which it seeks such documents. Third, for each request, a company will only have to produce documents and information about specific drug products that are listed in each company's information collection request, rather than for "all products as to which the generic company has made a Paragraph IV certification." Geneva Comment at 3. Thus, Commission staff continues to believe that the estimates provided above are reasonable.

13. Estimated Capital/Other Non-Labor Cost Burden

The capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may require that respondents retain copies of the information provided to the Commission, 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 diskettes, photocopier toner, or paper in order to comply with the Commission's requests. Staff estimates that each respondent will spend $500 for such costs regarding the information request, for a total additional non-labor cost burden of $45,000 ($500 x 90 companies).

14. Estimate of Cost to 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. These are known costs. However, 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[27] and the actual amount of time needed to complete the study. Nonetheless, staff estimates that approximately two attorney work years, 500 economist hours, and one research assistant work year will be necessary to complete the study and that the total remaining cost to the Commission will range between $325,000 and $375,000. 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

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 after the completion of the

[27] 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.

OMB review process. The projected duration of the information collection is approximately six weeks. The estimated date for the completion of the report is mid-to-late 2001.

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.

APPENDIX A

Initial notice seeking public comment on the study
65 Fed. Reg. 61,334 (Oct. 17, 2000)

APPENDIX B

Revised request(s) for the innovator and generic companies

Questions To Be Asked of Innovator and Generic Drug Companies

Questions for Innovator Companies:

1. The subscriber to your report is to give his or her full name and business address and state his or her official capacity.

2. State the full name of the company and its official address, and its date and state of incorporation.

3. State whether the company is a subsidiary company; whether the company has a subsidiary company(ies); and report the same information specified in item (2) regarding each parent or subsidiary.

For each of the following questions (4-8), the following definitions apply:

(a) the term "ANDA" means Abbreviated New Drug Application, as defined by 21 U.S.C. § 355(j).

(b) the term "Drug Product" means each finished dosage form of the drug the company has listed in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") (regardless of whether the Drug Product is currently listed in the Orange Book) and specifically includes those Drug Products including the following active ingredients: (a list of such active ingredients will be tailored specifically for each company).

(c) the term "person" means any natural person, corporate entity, partnership, association, joint venture, or trust which is engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any Drug Product.

(d) the term "relating to" means in whole or in part constituting, containing, concerning, discussing, describing, analyzing, identifying or stating.

(e) the term "sales" means net sales, i.e., total sales after deducting discounts, returns, allowances and excise taxes. "Sales" includes sales of the Drug Product whether manufactured by the company itself or purchased from sources outside the company and resold by the company in the same manufactured form as purchased.

4. Submit all agreements between the company and any person (including corporations or other business entities acquired since the agreement(s) was (were) executed) executed

after December 31, 1994,[1] relating to an ANDA involving any Drug Product, where the company holds the rights to the NDA corresponding to the ANDA that is the subject of the agreement. Examples of such agreements include, but are not limited to: (a) patent litigation settlements (full or partial) between the company and persons that have filed an ANDA involving any Drug Product; (b) agreements related to the filing (or non-filing) of an ANDA by any applicant (or potential applicant) involving any Drug Product; (c) licensing agreements between the company and persons that have filed an ANDA involving any Drug Product; and (d) agreements related to any acquisition, divestiture, joint venture, alliance, license or merger by the company of any business involving the research, development, manufacture or sale of any Drug Product that is the subject of an ANDA. The company is not required to submit purchase orders for raw material supplies, equipment and facility contracts, or employment or consulting contracts, nor is the company required to submit agreements executed after the generic manufacturer had begun commercial marketing of the generic Drug Product corresponding to the ANDA for which it had received FDA approval. The company also is not required to submit information that has already been submitted to the Commission pursuant to the Premerger Notification Rules (16 CFR Parts 801-803 (2000)) and Section 7A of the Clayton Act (15 U.S.C. 18a), or Sections 6, 9, 13, and 20 of the Federal Trade Commission Act (15 U.S.C. 46, 49, 53, and 57b-1), although the company must identify such information as having been previously submitted. For any such agreement submitted, also submit all studies, surveys, analyses and reports that were prepared by or for any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluate or analyze the reasons for making such agreement (or any of the provisions in such agreement), and indicate (if not contained in the document itself) the date of preparation, and the name and title of each individual who prepared each such document.

5. Identify all patents that the company has filed in the Orange Book and the date of listing (regardless of whether currently listed in the Orange Book) relating to each Drug Product for which the company has been notified of the filing of an ANDA by another person. Indicate if the patent(s) was (were) filed in the Orange Book after the company received approval of the New Drug Application, as defined under 21 U.S.C. 355(b) et seq., for the Drug Product. Also submit a copy of each such patent identified and identify whether the patent is owned by, assigned to, or licensed to the company.

6. Identify and list all lawsuits (including the court, date filed, docket number, parties, current or final status (including dates), current or final docket sheet, any reporter cites;

[1] As well as such agreements that were executed prior to January 1, 1995 but remain in force as of the date of the information collection request.

and any appellate history relating to the lawsuit) to which the company is or was a party that involve an ANDA paragraph IV certification related to any Drug Product. Submit the complaint, the answer, any motion(s) for summary judgment, any pretrial memoranda, and any court orders and opinions on any dispositive issue for each such lawsuit.

7. For each Drug Product for which the company has been notified that an ANDA containing a paragraph IV certification had been filed with the FDA, state the company's sales, in units and dollars, by each finished dosage form for each calendar year since, and including, the year the company was notified of the filing of such ANDA. If the company has its own generic version of the Drug Product, separate the sales for the branded product and the generic product.

8. For each Drug Product for which the company has been notified that an ANDA containing a paragraph IV certification has been filed with the FDA, state whether the company has filed, or contributed to the filing of, in whole or in part (e.g., provided funds, legal or regulatory assistance to support the filing), a citizen petition with the FDA concerning an ANDA related to that Drug Product and identify the FDA docket number assigned to such citizen petition.

Questions for Generic Companies:

1. The subscriber to your report is to give his or her full name and business address and state his or her official capacity.

2. State the full name of the company and its official address, and its date and state of incorporation.

3. State whether the company is a subsidiary company; whether the company has a subsidiary company(ies); and report the same information specified in item (2) regarding each parent or subsidiary.

For each of the following questions (4-8) the following definitions apply:

(a) the term "ANDA" means Abbreviated New Drug Application, as defined by 21 U.S.C. § 355(j).

(b) the term "Drug Product" means each finished dosage form of the drug listed in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") (regardless of whether the Drug Product is currently listed in the Orange Book) and specifically includes

those Drug Products including the following active ingredients: (a list of such active ingredients will be tailored specifically for each company).

(c) the term "Innovator Company" means each person or company (including its predecessors in interest, subsidiaries, affiliates, successors, and assigns) that has filed a New Drug Application (NDA), as defined under 21 U.S.C. § 355(b) et seq. for any Drug Product, or holds the rights to any such NDA.

(d) the term "person" means any natural person, corporate entity, partnership, association, joint venture, or trust which is engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any Drug Product.

(e) the term "relating to" means in whole or in part constituting, containing, concerning, discussing, describing, analyzing, identifying or stating.

(f) the term "sales" means net sales, i.e., total sales after deducting discounts, returns, allowances and excise taxes. "Sales" includes sales of the Drug Product whether manufactured by the company itself or purchased from sources outside the company and resold by the company in the same manufactured form as purchased.

4. Submit all agreements between the company and any person (including corporations or other business entities acquired since the agreement(s) was (were) executed after December 31, 1994,[1] relating to any ANDA involving any Drug Product. Examples of such agreements include, but are not limited to: (a) patent litigation settlements (either full or partial) between the company and any Innovator Company; (b) agreements between the company and any other person related to the filing (or non-filing) of an ANDA by the company involving any Drug Product; (c) licensing agreements entered into with any Innovator Company; and (d) agreements related to any acquisition, divestiture, joint venture, alliance, license or merger by the company of any business involving the research, development, manufacture or sale of any Drug Product that is the subject of an ANDA. The company is not required to submit purchase orders for raw material supplies, equipment and facility contracts, or employment or consulting contracts, nor is the company required to submit agreements executed after the company had begun commercial marketing of the generic Drug Product corresponding to the ANDA for which it had received FDA approval. The company also is not required to submit information that has already been submitted to the Commission pursuant to the Premerger Notification Rules (16 CFR Parts 801-803 (2000)) and Section 7A of the Clayton Act (15 U.S.C. 18a), or Sections 6, 9, 13, and 20 of the

[1] As well as such agreements that were executed prior to January 1, 1995 but remain in force as of the date of the information collection request.

Federal Trade Commission Act (15 U.S.C. 46, 49, 53, and 57b-1), although the company must identify such information as having been previously submitted. For any such agreement submitted, also submit all studies, surveys, analyses and reports that were prepared by or for any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluate or analyze the reasons for making such agreement (or any of the provisions in such agreement), and indicate (if not contained in the document itself) the date of preparation, and the name and title of each individual who prepared each such document.

5. Identify and list all lawsuits (including the court, date filed, docket number, parties, current or final status (including dates), current or final docket sheet, any reporter cites, and any appellate history relating to the lawsuit) to which the company is or was a party involving an ANDA containing a paragraph IV certification. In those cases in which the company is not the sole defendant, describe how litigation expenses are or have been distributed among the defendants.

6. Identify when the company first began commercial marketing of a generic version of any Drug Product approved by the FDA, by each finished dosage form (or, if applicable, indicate that no such commercial marketing has occurred). Identify when the company received tentative and final approvals from the FDA for such Drug Product.

7. Identify each instance in which the company has asserted before a court or before the FDA that a patent was improperly or untimely listed in the Orange Book as defined in 21 U.S.C. 355(b) or (c). For each such assertion, submit the pleading(s) in which such assertion was made and any responsive pleading(s).

8. For each Drug Product for which the company has filed an ANDA containing a paragraph IV certification, state the company's sales (if any), in units and dollars, by each finished dosage form for each calendar year since, and including, the year the company received FDA approval of such ANDA.