

[Billing Code: 6750 - 01P]
FEDERAL TRADE COMMISSION
Agency Information Collection Activities; Comment Request

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

ACTION: Notice.

SUMMARY: The FTC is considering conducting a study to analyze the use and likely short- and long-run competitive effects of authorized generic drugs in the prescription drug marketplace. Before investigating these issues, the FTC is soliciting public comments on its proposed information requests to firms in the prescription drug industry. These comments will be considered before the FTC submits a request for Office of Management and Budget (“OMB”) review under the Paperwork Reduction Act (“PRA”), 44 U.S.C. 3501-3520.

DATES: Comments must be received on or before June 5, 2006.

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

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC website, to the extent practicable, at www.ftc.gov. As a matter of discretion, the FTC makes every effort to remove home contact information for

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

individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.htm>.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Michael S. Wroblewski, Assistant General Counsel, Policy Studies, 600 Pennsylvania Avenue, NW, Washington, DC 20580; telephone (202) 326-2155.

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

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

At that point, the first-filed paragraph IV ANDA applicant becomes entitled to a 180-day marketing exclusivity period, during which the FDA cannot approve any other, later-filed paragraph IV ANDA for a generic drug corresponding to the same brand-name drug product.² This protects the first FDA-approved paragraph IV ANDA applicant from competition with other generic ANDA applicants during this time.

The 180-day marketing exclusivity period does not preclude competition from NDA-approved “authorized generics,” however.³ An authorized generic is chemically

² The 2003 Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108-173) revised the precise conditions under which the FDA can approve a later-filed ANDA. In general, the exclusivity period lasts until 180 days after (1) the first commercial marketing of the first applicant’s generic drug, or (2) a decision of an appellate court holding the brand-name company’s patent(s) invalid or not infringed.

³ *Teva Pharm. Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed in a generic version under the NDA-approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic. The trade dress typically differs for the brand-name drug and its authorized generic equivalent, but the drug product is exactly the same.

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

Currently, there is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition.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 marketplace.”⁶

The Commission proposes to undertake such a study, as described in this notice, to examine both the likely short-term competitive effects of authorized generic drug entry

⁴ A recent paper by Ernst R. Berndt, et al., funded by Johnson & Johnson, discusses the issues involved, but relies solely on data for three drug products as the bases for its conclusions that authorized generics benefit consumers and are unlikely to harm competition. An October 2005 paper by David Reiffen, et al., studies the magnitude of the effect of authorized generic entry on generic price, but does not measure this effect directly and uses data from the late 1980s and early 1990s. The proposed study would include a more robust and up-to-date analysis of the competitive effects of authorized generics based on actual company data.

⁵ See Letter to Chairman Deborah Platt Majoras, from Senators Grassley, Leahy, and Rockefeller (May 9, 2005).

⁶ See Letter to Chairman Deborah Platt Majoras from Representative Henry A. Waxman (Sept. 13, 2005).

and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers.⁷ Among other things, the proposed study will examine actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; business reasons (including profitability assessments) that support authorized generic entry; factors (including product development and litigation costs) relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration; and licensing agreements with authorized generics. These data will enable the proposed study to make new contributions to the economic literature on the effects of generic drug entry on prescription drug prices and, in particular, the role of the 180-day period of exclusivity in generic competition prior to patent expiration.

To obtain the relevant data, the Commission proposes to send special orders pursuant to Section 6(b) of the FTC Act, 15 U.S.C. 46(b), to brand-drug companies with products that have first faced generic competition since January 1, 1999;⁸ generic drug companies that have marketed authorized generic drugs since January 1, 1999 (“authorized generic companies”); and generic drug companies that have filed an ANDA containing paragraph III and IV certifications since January 1, 1999 (“independent generic companies”). The Commission has entered into an agreement with the FDA to obtain information to identify the brand-drug companies and independent generic companies that meet these criteria. Information received from the brand-name companies in response to the special orders will permit the Commission to issue subsequent special orders to authorized generic companies. Based on a preliminary analysis, approximately 80 brand-name drug manufacturers, 10 authorized generic drug companies, and 100 independent generic companies meet these criteria.

Under the PRA, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. “Collection of information” means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. § 3502(3), 5 CFR § 1320.3(c). As required by the PRA, 44 U.S.C. § 3506(c)(2)(A), the FTC is providing this opportunity for public comment before requesting that OMB grant clearance for this survey.

⁷ In its 2002 study of how generic drug competition prior to patent expiration has developed, the Commission found that the Hatch-Waxman framework had promoted entry by low-cost generic drugs prior to patent expiration. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>> (“*Generic Drug Study*”).

⁸ We have chosen 1999 as the start of the study period because in 1998, the FDA changed its regulations governing eligibility for the 180-day exclusivity period in response to the decision in *Mova v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). Since then, the FDA has granted the 180-day exclusivity to substantially more generic applicants than it had previously. *Generic Drug Study* at 57. This proposed study, therefore, will be based on this altered regulatory landscape.

The FTC invites comment on the following: (1) whether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility; (2) the accuracy of the FTC's estimate of the burden of the proposed collections of information; (3) ways to limit the number of companies included in the study without undermining the validity and reliability of the study results (*e.g.*, reduce the number of drug products studied by only including those products in an oral solid form, eliminate those generic companies that have filed only one ANDA during the study period, reduce the study time period, etc.); (4) ways to enhance the quality, utility, and clarity of the information to be collected; and (5) ways to minimize the burden of collecting the information on those who are to respond, including through the use of collection techniques or other form of information technology, *e.g.*, permitting electronic submissions of responses. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before June 5, 2006.

A. Description of the Collection of Information and Proposed Use

The FTC proposes to send information requests to approximately 80 brand-name drug manufacturers, 10 authorized generic drug companies, and 100 independent generic companies. As described above, 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 that have received notice of the filing of an ANDA, as defined by 21 U.S.C. § 355(j)(IV), as to one or more of their products since January 1, 1999. The FTC also proposes to send special orders to generic drug companies that have marketed authorized generic drugs since January 1, 1999. In addition, the FTC proposes to send special orders to generic drug companies that filed an ANDA since January 1, 1999.

In addition to routine questions about the name, address, organization chart(s), and incorporation date of the responding company and its subsidiaries, and the name, business address, and official capacity of the official supervising the company's response, the FTC will ask the three different company types to provide answers to the following questions for a list of specific drug products that the FTC will provide:

Brand-Name Companies:

1. For each identified drug product, submit any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and 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 (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed how to respond (including through pricing changes) to (a) future or current generic competition, (b) the expiration of the patent(s) claiming

the identified drug product or its use, (c) whether to license or otherwise market the identified drug product as an authorized generic drug product, and/or (d) whether to refrain from marketing an authorized generic, including but not limited to, agreements to do so. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, indicate (if not contained in the document itself) the date of preparation and the name and title of each individual who prepared the document, and group the documents by identified drug product. If the company licensed or otherwise authorized the marketing of the identified drug product as an authorized generic, provide the license agreement with the authorized generic company and the supplemental application the company filed with the FDA pursuant to 21 U.S.C. § 356a(b) that had the effect of allowing the company to license or otherwise market the identified drug product as an authorized generic.

2. For each identified drug product, provide the following information:
 - a. a detailed description of the product, including its brand name or identification number, its common name, and its biological or chemical class; its application status at the FDA for each of its indication(s) or end use(s), and intended indication(s) or end use(s), including the date the New Drug Application was filed and approved, and the date the product was first marketed in the United States, as both a brand-name drug and, if applicable, an authorized generic;
 - b. a detailed description of every SKU of the product as both a brand-name drug and, if applicable, an authorized generic, including product form, dosage strength, bottle or box size, route of administration, and the date first marketed in the United States;
 - c. the identification number of each SKU of each product;
 - d. a list of all patents listed in the Orange Book for each drug product whether owned, licensed, or controlled by the company, including patent or patent application number, title, priority date, inventor, date filed, date issued, date of patent expiration, status, and a copy of all relevant claims.
3. For each SKU listed in response to Specification 2c above, state for every month from a full calendar year preceding generic entry to the present, for sales in the United States (*e.g.*, if generic entry occurred in July 2002, the company is to provide the following information for every month beginning January 1, 2001):
 - a. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;

- b. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;⁹
- c. the company's standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;
- d. the company's prices, including: (1) list price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services.

Authorized Generic Company Questions [If a Brand Drug Company uses a subsidiary, division, or affiliated company to distribute the authorized generic drug, the "company" referred to in these questions is that subsidiary, division, or affiliated company.]:

- 1. For each identified drug product that is licensed to, or otherwise marketed by, the company:
 - a. provide any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and 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 (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, including discussion related to whether to file an ANDA containing a paragraph III or IV certification (regardless of whether the company filed such ANDA), whether or when to launch commercial marketing, and the impact that entry by an authorized generic drug would have on generic entry by an ANDA drug product. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, 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;

⁹ Prescription drugs distributed through hospitals, clinics and long-term care facilities may have different pricing structures than those distributed through retail and mail-order pharmacies.

- b. provide a copy of the license agreement, or other marketing authorization, with the brand-name company.
2. For each identified drug product that is licensed to, or otherwise marketed by, the company, provide the following information:
 - a. a detailed description of every SKU of the product, including product form, dosage strength, bottle or box size, route of administration, and the date first sold in the United States;
 - b. the identification number of each SKU of each product.
3. For each SKU of each relevant product listed in response to Specification 2b above, state for every month from the date of first commercial marketing to the present, for sales in the United States:
 - a. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;
 - b. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;
 - c. the company's standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;
 - d. the company's prices, in each relevant area, including: (1) list price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services.

Independent Generic Company Questions:

1. For each identified product, and for any other brand drug product for which the company has evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, submit the following:
 - a. any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and 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 (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, including discussion related to (a) whether to file an ANDA containing a paragraph III or IV certification (regardless of whether the company filed such ANDA), (b) whether or when to launch commercial marketing, and/or (c) the impact that entry by an authorized generic drug would have on generic entry by the company's ANDA drug product. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, 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. Submit a copy of the ANDA application for each identified drug product;

- b. any documents sufficient to show the identified product's development costs, costs to file ANDA, and patent-related litigation costs.

2. For each identified product, state the following:

- a. a detailed description of the product, including its brand name or identification number, its common name, and its therapeutic class; its application status at the FDA for each of its indication(s) or end use(s), and intended indication(s) or end use(s), including the date the application was filed and approved, and the date the product was first sold in the United States;
- b. a detailed description of every SKU of the product, including product form, dosage strength, bottle or box size, route of administration, and the date first sold in the relevant area;
- c. the identification number of each SKU of each product.

3. For each SKU listed in response to Specification 2c, state for every month from the date of first commercial marketing to the present, for sales in the United States:

- a. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;
- b. the company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;

- c. the company's standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;
- d. the company's prices, in each relevant area, including: (1) list price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services.

For All Three Company Types

The FTC will request IMS Health (IMS) data if the company obtains such information in the regular course of business, as follows:

If the company obtains IMS Health (IMS) data in the regular course of business, provide for each identified drug product, for every month from January 1999 (or date of first commercial marketing, where applicable) to the present for sales in the United States:

- a. IMS Retail Perspective data, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to independent pharmacies, chain pharmacies, mass merchandisers, proprietary stores, and food stores with pharmacies;
- b. IMS Provider Perspective data, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to, non-federal hospitals, federal facilities, mail order, and long-term care facilities, clinics, and closed wall HMOs;
- c. IMS National Prescription Audit data, or the equivalent thereof, by product form, by strength, and by diagnosis, for newly dispensed prescriptions, refill dispensed prescriptions, total dispensed prescriptions, total units, and total dollar sales;
- d. IMS Retail Method of Payment Report, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to, private managed care, and public managed care;

- e. IMS Integrated Promotional Services Total Promotion Report, by product form, for total dollars spent for: (1) detailing; (2) physician and pharmacist marketing; (3) medical and other journal advertising; and (4) any other promotional spending, including, but not limited to, direct consumer advertising;
- f. any other IMS data, or the equivalent thereof, used in the ordinary course of business;
- g. all supporting definitions and materials for any IMS data provided.

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). The FTC will use available information technology (*e.g.*, electronic submission of financial information) to ease the collection of the requested information.

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

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

B. Estimated Burden Hours

The FTC proposes to use three different sets of questions for the three drug company types: brand-name companies, authorized generic companies, and independent generic companies. The drug products that the FTC will study will be identified for each company. Although the questions vary, the FTC does not anticipate this will have a significant effect on the effort required to respond to them.

The FTC has estimated three average response times depending upon the number of drug products for which the 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. The FTC anticipates that the majority of burden hours will be primarily to search, retrieve, and copy relevant documents necessary to answer question number 1 for each of the company types, and that the hours necessary to obtain the financial information will not vary depending upon the number of drug products. The total estimated burden to answer the questions and to produce documents based on the number of drug products identified for each company is based on the following:

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	12	36	80
Retrieve and copy requested documents	40	60	120
Identify requested financial information	40	50	60
Obtain financial information	12	16	20
Prepare response	24	40	80
Total	140 hours	226 hours	408 hours

Based on preliminary information, the FTC anticipates that it will seek information about 1 to 5 drug products from approximately 130 companies, for 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 39,040 hours (140 hours x 130 companies + 226 x 20 companies + 408 hours x 40 companies).

C. Estimated Cost Burden

It is not possible to calculate with precision 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. 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 \$35,000 (140 hours x \$250/hour) and \$102,000 (408 hours x \$250/hour).

The FTC estimates that the capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may require that respondent 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.

By direction of the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary