PhRMA Comments
On Proposed Information Requests

Authorized Generic Drug Study
FTC Project No. P062105

June 5, 2006

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INTRODUCTION

The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby submits comments on proposed information requests for a Federal Trade Commission ("FTC") study to analyze the competitive effects of authorized generic drugs.[1] PhRMA represents the United States' leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.[2]

The proposed empirical study will show whether authorized generics benefit consumers by lowering prices for generic drugs. As stated in its notice, the FTC will conduct an empirical, data-driven analysis of the competitive impact on consumers of authorized generics. The proposed information requests for this empirical study should be revised in several areas to enable the FTC to focus on the most pertinent data while reducing the burden on respondents. These revisions can be made while ensuring that the FTC receives the data it needs to assess the actual effects of authorized generics in the marketplace.

I. THE INFORMATION REQUESTS SHOULD BE CLOSELY TAILORED TO THE OBJECTIVE OF THE STUDY

In accordance with the Paperwork Reduction Act, the FTC has invited comments on the proposed information requests taking into account: (1) the necessity of the information, including its practical utility, (2) the accuracy of the FTC's estimate of the burden imposed by the information requests, (3) ways to limit the number of companies, (4) ways to enhance the quality, utility, and clarity of the information, and (5) ways to minimize the burden.[3] An evaluation of these factors requires that close consideration be paid to the stated purpose of the study.

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[1] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, Mar. 29, 2006, www.ftc.gov.

[2] A full list of members can be found at www.phrma.org.

[3] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 5, Mar. 29, 2006, www.ftc.gov.

The purpose of the study, as requested by Senators Grassley, Leahy and Rockefeller, is to evaluate "the short term and long term *effects on competition* of the practice of 'authorized' generics."[4] Likewise, Representative Waxman has requested a study of "*the impact* of so-called 'authorized generics' on competition in the prescription drug marketplace."[5] Thus, the study has been conceived to analyze the actual competitive effect or impact of authorized generics.

Based on empirical data, the FTC's economic study should enhance public understanding of how authorized generics impact consumers. As the FTC stated, "[c]urrently, 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."[6] While a few economists have published papers on authorized generics, "[t]he proposed study would include a more robust and up-to-date analysis of the competitive effects of authorized generics based on actual company data."[7] The FTC has explained to Congress that this study will "build on the economic literature about the effect of generic drug entry on prescription drug prices."[8]

As explained below, the proposed requests call for information that lacks practical utility for the authorized generic drug study that Congress requested. This includes broad requests for documents that relate generally to competition between brand name and generic drug companies.

II. DATA, RATHER THAN DOCUMENTS, BEST MEET THE NEEDS OF THE STUDY

Given the purpose of the study, the most relevant information is data, particularly pricing data and output data bearing directly on the analysis of entry and competitive effects. Data showing patterns of generic entry in the presence of an authorized generic is central to the FTC's

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[4] *Id.* at 3 (quoting letter from Senators Grassley, Leahy, and Rockefeller) (emphasis added).

[5] *Id.* (quoting letter from Representative Waxman) (emphasis added).

[6] *Id.*

[7] *Id.*

[8] FTC, Congressional Budget Justification, Fiscal Year 2007, at 10, Feb. 6, 2006, www.ftc.gov.

analysis and should answer most, if not all, of the questions posed by Congress regarding the potential competitive impact of authorized generics. The data will show most clearly and directly whether authorized generics have benefited consumers by increasing availability of prescription drugs at lower prices.

A number of the FTC's proposed document specifications call for the production of documents relating to the brand name drug companies' forward-looking plans for introducing authorized generics or for responding to entry of any generic drug product. By their nature, documents written in anticipation of generic entry are not well suited to assess and measure the actual impact authorized generics have had on marketplace pricing or output. Subjective observations made in documents by company representatives are difficult to assess and evaluate for an empirical study of this nature. Documentary observations cannot be aggregated and apportioned (or weighted) like pricing or output data. Isolated or scattered subjective observations are of little utility for a long-term empirical study.

The scope of the study – covering 180 different companies and spanning 8-9 years – makes the use of documentary observations even less practical for assessing the impact on consumers. Assigning appropriate credit or weight to particular documentary observations will require the FTC to evaluate the document or sources (e.g., 1 brand name company vs. 30 brand name companies), the time period (e.g., 1999 vs. 2005 or 1999 vs. 2002-2005), and the business purpose and credibility of the documentary observations (e.g., whether the observation was based on accurate and complete information and whether senior management relied on the observation in its decision-making). The FTC cannot easily assess the credibility of documentary observations or statements from a document production alone and cannot do the type of investigation (covering 180 companies over 8-9 years) needed to assess this type of evidence.

The proposed requests for speaking documents differ from prior FTC studies in this industry. The FTC's most recent comprehensive study of generic drug competition properly

focused on data instead of documents.[9] Like this proposed study, the earlier generic drug study followed a request from Congress, authorization from the Office of Management and Budget in accordance with the Paperwork Reduction Act, and the issuance of special orders to brand name and generic drug companies under § 6(b) of the FTC Act.[10] The special orders developed by the FTC for that generic drug study covered data focusing on actual generic drug entry in the marketplace.[11]

While data-focused, the FTC's earlier special orders called for far less documents than the proposed requests for this study. The prior study asked brand name companies for two discrete types of documents: (1) agreements the company entered into that relate to an Abbreviated New Drug Application (ANDA) and (2) officer or director level analyses concerning the company's evaluation of those particular ANDA related agreements.[12]

The prior study focused on generic drug entry but did not require brand name drug companies to collect, produce, and catalog documents relating to their perceptions of entry conditions or potential or prospective entry. Rather, the FTC relied on data and a limited set of core documents concerning actual entry in the marketplace.

III. TO THE EXTENT THE FTC SEEKS DOCUMENTS, THE FOCUS SHOULD BE ON GENERIC DRUG COMPANY DOCUMENTS

The proposed document requests treat brand name companies and generic drug companies substantially the same. This symmetrical approach does not serve the study's purpose. A fundamental purpose of the study is to assess whether the sale of low priced authorized generics has prevented or hindered entry by generic drug companies. Entry analysis is

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[9] *See* Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, www.ftc.gov.

[10] *Id.* at Ch. 1 at p. 1-3, Appendix E.

[11] *Id.* at Appendix E.

[12] *Id.*

based on the costs incurred by companies seeking to enter and their likely profits or return on investment as a result of entry.[13] It entails a systematic analysis of likely costs and returns.[14]

The best documentary source for information on the costs and profitability of entry is generic drug company documents. The generic drug companies' market analyses, studies, surveys, and reports will most directly respond to the core question of whether authorized generics have removed the companies' financial incentives to enter. These documents will describe the product development costs, the costs to file ANDAs, patent litigation costs and patent litigation financing arrangements, and other cost considerations for entering. Likewise, the documents from generic drug companies will describe the return on investment or profitability of entry. The generic drug company documents are most likely to show whether they have abandoned plans to enter after the commercial release of authorized generics caused prices to drop too low, whether their expected return on investment has declined too much, or whether neither scenario has developed.

In contrast, the speaking documents of brand drug companies lack relevance for this analysis focusing on the costs and profitability of entry. The state of mind, motivation, or intent of brand name drug companies is immaterial to the question of whether generic drug companies have been able profitably to enter or expand. Companies often introduce new products with the motivation or intent of gaining business from rivals. They may believe that the new products will grow rapidly in sales. They may believe that competitors will falter. But these subjective beliefs are no substitutes for hard evidence of whether entry remains financially viable. Measuring the competitive impact of newly-released products (such as authorized generics) requires analysis of how rivals have in fact responded in the marketplace. This is far more

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[13] *See, e.g.,* Department of Justice and FTC Horizontal Merger Guidelines § 3, www.ftc.gov (discussing entry analysis in the merger context); *Rebel Oil Co., Inc. v. Auto Flite Oil Co. Inc.*, 51 F.3d 1421, 1439 (9th Cir. 1995) (discussing entry analysis in the monopolization context); Areeda & Hovenkamp, Antitrust Law § 409, Supp. 1992 (overview of entry analysis).

[14] *Id.*

important than ascertaining the beliefs of representatives from the company that released the new authorized generic product.

Moreover, any documents from brand name drug companies that contain the relevant factual analyses – analyses of the costs of entry and expected return on investment or profitability of entry – are inherently speculative, and therefore only indirectly probative, at best. The best and most reliable evidence will come from the generic drug companies that have analyzed whether to incur the costs of entering given the return on investment they expect.

The FTC should account for the burden and costs of complying with document requests as well as the limited practical utility of speaking documents from brand name drug companies. Compared to the data requests, the document requests will impose far greater costs on the brand name drug companies and provide less practical and useful information for the FTC's entry analysis. Even under the FTC's estimates, the costs of complying with the document requests far outweigh those of the data requests.[15] Responding to the document requests will require greater input from company management and larger outside legal expenses than responding to data requests. From preparation of privilege logs to email retrieval over years, the document requests will impose significant costs. Indeed, review for and cataloging of privileged documents will likely be a significant burden, as it is likely that many of the documents within the scope of the FTC's broad requests will have been created in the context of anticipated or pending patent litigation. The estimates of expense included in the FTC notice are significantly lower than what would likely be incurred in responding to the proposed document requests.

The potential benefit of documents from brand name drug companies does not justify the costs that the companies will incur. Speaking documents from representatives of the brand name drug companies are unlikely to contribute to a robust empirical study designed to build upon the

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[15] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 12, Mar. 29, 2006, www.ftc.gov.

economic literature. The FTC should conduct the empirical study without compelling production of speaking documents from brand name drug companies.

IV. IF INCLUDED, DOCUMENT REQUESTS DIRECTED AT BRAND NAME DRUG COMPANIES SHOULD BE NARROWED

The special orders for the authorized generic drug study should be data focused. The FTC's proposed document requests are overbroad and would place an undue burden on brand name drug companies. In particular, the FTC's estimates understate by several multiples the amount of time and money it would likely take to comply with the requests as written. The eight-plus year time period the FTC contemplates would place significant burdens on PhRMA's members, many of whom have undergone substantial corporate changes during the past eight years. Searching outdated files would be time consuming and would not result in materially useful information.

To the extent the FTC requests documents from brand name drug companies, it should focus on documentary analysis of actual competition that has occurred in the marketplace. We recommend limiting the document requests as follows:

Suggested Changes	Reasons for Changes
For each identified brand name drug product for which an authorized generic has been marketed, submit ~~any documents, including~~ studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998, were not prepared in anticipation of litigation or for trial, and are maintained in the files of ~~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~~ current 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 that has occurred in the marketplace as a result of or following the entry of an authorized generic drug product or (b) ~~the expiration of the patent(s) claiming the identified drug product or its use~~ generic drug entry or exit that has occurred in the marketplace~~, (c) whether to license or otherwise market the~~	• Greater focus on authorized generic competition • Focus on current officer and director level documents • Limited utility of future competition documents • Reduced burden in conducting

~~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 or exit that has occurred in the marketplace for either specified products or ~~responses to generic entry in general.~~ other products. Documents provided shall be submitted as found in the company's officers' or directors' files. Provide a master list showing: (a) the name of each person from whose files responsive documents are submitted and (b) the corresponding document control numbers used to identify each person's documents. ~~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. § 356(b) that had the effect of allowing the company to license or otherwise market the identified drug product as an authorized generic.	document search and review • Reduced burden in cataloging information about each document • Reduced burden in reviewing privileged litigation documents

These proposed changes will reduce the burden while enabling the FTC to meet its stated objective.

A. Documents Unrelated to Authorized Generics Are Unnecessary

Any document requests should be focused exclusively on those drug products for which a company has manufactured or licensed an authorized generic that has been sold in the marketplace. Otherwise, the requests would call for boxes and boxes of speaking documents that relate generally to brand vs. generic drug competition. This would encompass large volumes of documents unrelated to authorized generics.

PhRMA proposes changing the scope of the document requests from "each identified drug product" to "each identified brand name product for which an authorized generic has been marketed". The FTC can make this change to the scope of the document requests without undermining its study of the relevant data. The document requests (and not necessarily the data requests) can and should be limited this way.

As to data, the FTC's notice indicates that it "will examine actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics . . . ."[16] As such, the study will compare data on pricing of identified drug products without authorized generics versus pricing with authorized generics. To make this data comparison, the FTC may have a need for pricing data for identified drugs with and without competition from authorized generics.

It does not follow, however, that the FTC should compel production of documents for brand name drugs that have never faced competition from authorized generics. Going back to 1998, the brand name drug companies will likely have documents that speak generally about competition between brand name drugs and Paragraph IV generic drugs. These kinds of documents are not reasonably likely to contribute to a robust economic study focused on the competitive impact of authorized generics. The significant additional burden of collecting and reviewing documents for all identified drugs is not justified based on the study's objective. The document requests as drafted would reach too many documents unrelated to any competition involving authorized generics.

Thus, the document requests should be changed so as to focus on drug products for which a company has commercially marketed an authorized generic. This change can be implemented while still seeking data for a broader range of identified drug products for purposes of a comparative analysis of pricing data.

B. Prospective, Potential, or Future Competition Documents Lack Practical Utility

Documents by company representatives about potential, prospective, or future competition are far less relevant than retrospective analyses describing observable competitive behavior of firms in the industry. The focus of any document analysis should be the actual or

[16] *Id.* at 4.

observable competitive impact – i.e., the impact on pricing, output, and entry – of authorized generics.

The draft document requests would cover "future . . . generic competition" documents, documents that discuss "how to respond" in the future to "the expiration of patent(s)", and documents that discuss "whether to license" or "whether to refrain from marketing an authorized generic" in the future.

Thus, the current draft requests would require production of documents that contain observations about potential or prospective competition. For example, the companies would need to produce a document prepared in 2000 in which a company representative spoke about potential or future events that would lead to a change in the competitive landscape in 2002 and how the company might respond to these changes in the future. This document would be responsive under the current draft regardless of whether the potential event occurred and regardless of whether the company responded in the marketplace as the 2000 document suggested that it might or would.

These types of prospective documents add little to the study of the competitive impact in the marketplace of authorized generics.[17] Any request for speaking documents should focus on retrospective analyses of observable events or occurrences affecting consumers in the marketplace – such as price competition between a company that commercially marketed an authorized generic and a company that marketed a Paragraph IV generic.

The proposed changes would cover documents concerning "competition that has occurred in the marketplace" for product categories in which a company has commercially marketed an

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[17] Recent legislative changes could further diminish the relevance of documents speaking about future or potential competition involving authorized generics. A few months ago, Congress passed the Deficit Reduction Act of 2005. *See* S. 1932, 109th Cong. § 6001(b)(1)(A). Effective in 2007, brand drug companies must include authorized generics in the calculation of average manufacturer's price and best price for purposes of Medicare reimbursement. *Id.* at § 6001(b)(1)(B), (b)(2). This could impact (next year and in future years) the incentives for brand drug companies to introduce authorized generics. At a minimum, it represents a change in the regulatory landscape that will not be reflected in companies' prospective analyses of the marketplace contained in documents prepared years ago.

authorized generic. It would also cover documents concerning "generic drug entry or exit" that has occurred in the marketplace. With those additions, it is unnecessary to have separate requests for documents about licensing attempts or future expiration of patents. Any competitively significant records in those areas will concern "generic entry or exit" or "competition that has occurred in the marketplace" relating to authorized generics.

C. The Document Requests Should Be Limited to the Files of Officers and Directors

The scope of the search for documents would depend heavily on how companies construe and apply the term "senior vice president (or equivalent position) with product line responsibility". The FTC should instead focus on documents maintained in the files of current officers or directors. This approach will avoid confusion, reduce the burden, and focus the review on the most probative company documents.

In both the generic drug entry study issued in 2002 and the pharmacy benefit manager (PBM) study published in 2005, the special orders issued by the FTC covered certain documents "prepared by or for any officer(s) or director(s) of the company".[18] These FTC studies did not require the companies to search for documents prepared "by or for" senior vice presidents or functional equivalents.[19] "The language 'by or for' embraces documents prepared by any persons, including consultants, for officers or directors."[20] Thus documents prepared by senior vice presidents or their equivalents (or other employees or consultants) would be responsive to a request for documents prepared "by or for" officers or directors when treated important enough to distribute to any company officer or director.

A modification to focus on current officer and director level documents will eliminate uncertainty and promote consistency in how companies respond. The FTC follows this approach

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[18] *See* Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies, Aug. 2005, Appendix A, www.ftc.gov; Generic Drug Entry Prior to Patent Expiration: An FTC Study, Appendix E, July 2002, www.ftc.gov.

[19] *Id.*

[20] Statement of Basis and Purpose, Premerger/HSR Act, Aug. 30, 1978, www.ftc.gov.

in its antitrust review of mergers and acquisitions. Under the Hart-Scott-Rodino Act (HSR) Act procedures, Item 4(c) of the HSR notification report requires production to the FTC of certain documents "prepared by or for an officer or director".[21] While various company employees may have titles that seem to be officer-level titles or perform tasks that seem to be officer-level tasks, officer status for HSR Item 4(c) purposes is not determined by title but by reference to the company's organizing documents. When those documents define and identify officers, the persons so identified are considered officers for purposes of Item 4(c).[22] When those documents empower the board to elect or appoint officers, persons so elected or appointed are also officers.[23]

At a minimum, the document requests should be narrowed to documents "prepared by or for" officers or directors, and not vice presidents or equivalents. The FTC can reduce the document searching and retrieval costs much more by limiting the production to documents "maintained in the files of current officers or directors" (rather than documents prepared "by or for" officers or directors). To identify potentially responsive documents prepared "by or for" officers or directors, many individual files (not just officer or director files) would need to be searched. Documents prepared "by or for" officers could reside in the files of hundreds of employees. Limiting the number of employees in the search group will substantially reduce the costs of complying with the document request. Indeed, the FTC has recently recognized that the number of employees in the search group is a critical factor impacting the costs of document productions.[24]

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[21] Instructions and Forms, Premerger/HSR Act, www.ftc.gov.

[22] Marion Bruno, FTC Premerger Office, Locating and Identifying 4c Documents, at 6, Apr. 2000; ABA Antitrust Section, Premerger Notification Manual, Opinion 280, 3rd ed. 2003.

[23] *Id.*

[24] FTC, Reforms to the Merger Review Process, Feb. 16, 2005 at 12-13, www.ftc.gov (adopting presumptive limits to the number of employees in the search group for merger investigations).

Any document search for this study should be limited to responsive documents "maintained in the files of current officers and directors" given the burden of the more expanded search coupled with the relative low practical utility of speaking documents. For a study of this nature, the document search should be less sweeping than HSR searches (which are narrower and transaction specific) required by the FTC and the Justice Department for the purpose of evaluating pending mergers and acquisitions. Including documents prepared "by or for" current and former vice president level employees would make the production far more sweeping.

D. Cataloging Detailed Information on Each Document Is Unduly Burdensome

The proposed request would require three categories of information for each responsive document: (1) the date of preparation, (2) name and title of each author of the document, and (3) the identified drug product to which it primarily relates.[25] To compile and catalog this information for each responsive document over the 8-9 year period will require a significant amount of time – beyond the FTC's estimated burden hours. For example, complying with these requests could require conducting interviews of multiple company employees and former employees about the authors of each document.

For Item 4(c) of the HSR notification form, the FTC requires information on the date and authors of each responsive document.[26] However, those document requests are much more targeted, involve far fewer documents, and are necessarily very limited in time frame. Companies must produce HSR documents concerning its review of a currently pending acquisition and thus HSR document productions typically cover just a few months or even just a few weeks. In contrast, the proposed document requests for the authorized generic study would reach back 8-9 years.

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[25] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, Mar. 29, 2006, www.ftc.gov.

[26] Instructions and Forms, Premerger/HSR Act, www.ftc.gov.

The FTC has recognized the burden of complying with instructions requiring that documents be grouped or sorted by specification or type of document (in this case, the identified drug product). Until 2002, the FTC required companies responding to second requests in merger investigations to sort documents by the specification to which each document was primarily responsive. The FTC eliminated this instruction in 2002 following concerns raised by the private sector about the burden and expensive relative to the utility of the information.[27] The instructions to the FTC model second request now allow for companies to respond based on how they maintain the documents in the regular course of business rather than by specification or document type.[28] The Federal Rules of Civil Procedure likewise allow for companies to comply with document requests based on how they maintain the documents in the regular course of business.[29]

Consistent with FTC and federal court practice, the proposed requests should be modified so as to eliminate the need for information by document on the current or former employees who were authors, the date, and the identified drug to which the document primarily relates. The requests should instead require that the documents be produced as they are maintained in the regular course of business along with a list or index identifying the person whose files the document came from.[30]

The Paperwork Reduction Act requires that each of the proposed document requests have "practical utility". 44 U.S.C. § 3506(c). Practical utility refers to "the actual, not merely the theoretical or potential, usefulness of information" for the particular agency project. 5 C.F.R. §

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[27] Statement of the Federal Trade Commission's Bureau of Competition on Guidelines for Merger Investigations, Dec. 2002, www.ftc.gov ("Documents Will No Longer Have to be Sorted or Identified by Specification .... producing documents to us in the order and sequence in which they are actually kept in the course of business is likely to reduce parties' burdens and expense without compromising our investigations").

[28] *Id.*; *see also* Bureau of Competition Releases Model Retail Second Request, Instruction P, Apr. 28, 2004, www.ftc.gov.

[29] Fed. R. Civ. P. 34(b).

[30] Bureau of Competition Releases Model Retail Second Request, Instruction P, Apr. 28, 2004, www.ftc.gov.

1320(l). The proposed document requests – by encompassing future competition documents, by focusing on documents unrelated or indirectly related to authorized generics, by reaching much deeper within the organizations than is customary, and by requiring a catalog of information relating to each responsive document –lack practical utility in light of the objective of this study.

V. IMS DATA CAN BE COLLECTED MORE EFFICIENTLY THROUGH OTHER MEANS

IMS data has been described "as the authoritative industry data source" [31] and has been relied upon by economists as a valuable source of pharmaceutical industry price and quantity data.[32] Based on IMS data and company pricing and output data, the FTC study of authorized generic competition should advance the economic literature and dispel misconceptions that are based on speculation rather than data. Nonetheless, the FTC should consider changing its current plans for collecting IMS data.

The FTC's proposal is to require 190 brand name and generic drug companies to make separate and independent productions of IMS data that the companies individually purchase from IMS Health. Customers of IMS Health include government agencies, financial analysts, and consultants as well as drug companies.[33] IMS Health sells its data under licenses that restrict licensees from disclosing the data to third parties.

For example, an FDA paper explains that "[t]his document contains proprietary data from IMS Health which cannot be shared outside of FDA without clearance from IMS Health . . . ."[34] The 190 companies would each need to get clearance from IMS that it can disclose the IMS data

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[31] *In the Matter of Schering Plough Corp.*, FTC Administrative Law Judge, Initial Decision ¶ 87, June 27, 2002. www.ftc.gov.

[32] David Reiffen & Michael R. Ward, Generic Drug Industry Dynamics, The Review of Economics and Statistics, 42, Feb. 2005 ("Our primary source for price and quantity data is Generic Spectra from IMS Inc., a proprietary vendor of information").

[33] IMS Health Annual Report at 7, 2005, www.imshealth.com.

[34] FDA Directors' Memorandum, Review of Risk Minimization Action Plan Submitted December 23, 2003, at 1, Aug. 4, 2004. www.fda.gov.

it has access to under its licenses. Assuming IMS would be willing to give such clearance, the 190 companies would then each separately be required to produce whatever data or subset of data is in their possession, all of which is coming from the same source (IMS Health).

A much more efficient procedure, consistent with the Paperwork Reduction Act, would be for the FTC to coordinate its access under a direct IMS license, if necessary, or through other government agencies. Taxpayers may have already purchased IMS data through other government agencies. For example, "[t]he FDA is a long-time user of IMS Health products and services."[35]

Working with IMS data under a license may provide the FTC with greater access to IMS personnel to assist in data interpretation, preparation of customized reports or data fields, or other data services.[36] The FTC should explore alternative ways to get the data directly from IMS Health before seeking separate IMS data productions from 190 different companies. Dealing directly with IMS Health will eliminate duplicative efforts and substantially reduce the overall burden of collecting IMS data for the study.

VI. COST ACCOUNTING DATA FROM BRAND NAME DRUG COMPANIES IS UNNECESSARY

Under the current proposal, eighty brand name companies would be required to provide, for each SKU of each identified product, "the company's standard or actual cost of good sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost,

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[35] FDA, Cooperative Agreements and Collaborative Resources, Appendix C, www.fda.gov; *see also* FDA, Generic Competition and Drug Prices, 2005, www.fda.gov (referring to "FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective, 1999-2004, extracted February 2005"); FDA, Gerald J. Dal Pan, Office of Drug Safety, June 14, 2004, www.fda.gov (referring to "Rx data . . . – IMS Health National Prescription Audit . . . – IMS Health National Disease and Therapeutic Index"); FDA, Project Manager, Office of Postmarketing Drug Risk Assessment, June 12, 2000, www.fda.gov (referring to "external collaboration with "IMS Health Data").

[36] Allison Masson and Robert L. Steiner, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws, FTC Bureau of Economics Study, at 7-8, Jan. 15, 1986 ("Our primary data are from the National Prescription Audit (NPA) compiled by IMS America . . . The magnitude and complexities of the data might have overwhelmed the project had not IMS America continued to provide patient answers to our multitudinous questions.").

overhead cost, other cost, and variances."[37] This cost accounting data by SKU would be required for the time period 1998 to the present.

The cost accounting and margin data of Paragraph IV generic drug companies may assist the FTC in its economic study, as that data may bear on the profitability of generic entry. Margin data from the generic drug companies may be relevant to assessing whether authorized generics has deterred generic entry by making it unprofitable, or not. But cost accounting and margin data for brand name drug companies will not show whether generic entry has become unprofitable. It is hard to see how margin data from brand drug companies has practical utility to the entry analysis.[38] Economic studies in this area have not focused on cost accounting data from brand drug companies, which differ from the generic drug companies undertaking the financial evaluation of whether to enter.[39]

Moreover, any analysis comparing the profitability of brand name drugs (or authorized generic drugs) with Paragraph IV generic drugs could be exceedingly difficult. Differences in cost accounting systems could greatly complicate such a comparative analysis, potentially involving 80 brand name companies and 110 generic companies over eight years. Brand name and generic companies may have different systems for allocation of rebates or refunds including rebates that may relate to multiple products. Cost accounting systems will differ significantly

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[37] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 7, Mar. 29, 2006, www.ftc.gov.

[38] While no one has suggested a theory of predatory pricing, a predatory pricing analysis could entail use of some margin data from brand name drug companies. The theory would be that brand name companies manufacture and sell (or license) authorized generics even though it is unprofitable for them to do so. Cost accounting data could be used in evaluating such a predatory pricing theory – a theory lacking any support in the economic literature, prior FTC enforcement actions, or any other credible source. Indeed, FTC leadership, as well as the Supreme Court, has seriously questioned any antitrust predation theory based on pricing low and operating unprofitably. *See* S. Creighton et al., *Cheap Exclusion*, 72 Antitrust L.J. 976, 977 (2005) (recommending greater enforcement focus on "cheap" exclusionary conduct rather "expensive predation (predatory pricing being our archetypal example)"); *Brooke Group v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 261 (1993) (rejecting antitrust claim that a competitor introduced generic cigarettes to lower price and profits and drive entrant from the marketplace in order to preserve branded cigarette profits).

[39] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 3 n.4, Mar. 29, 2006, www.ftc.gov (referring to Berndt paper and Reiffen paper).

across companies in techniques for measuring cost of goods sold; indeed the cost accounting systems may even differ significantly for a single company over time. Such differences could make a comparative analysis infeasible. This may be particularly true in the way different drug companies, especially brand name versus generic drug companies, record and account for rebates and promotional spending related to specific drug products.

PhRMA requests that the FTC carefully consider the necessity of cost accounting data from the brand name drug companies. For companies to comply with the cost accounting data requests may require a non-trivial amount of time and effort working with the current and predecessor or legacy cost accounting systems used during the 8-9 year time period. The FTC will likewise face significant challenges attempting to interpret cost accounting systems over time and across the many companies.

VII. THE FTC SHOULD REDUCE THE NUMBER OF DRUG PRODUCTS BY USING A STRATIFIED RANDOM SAMPLE

For each company, the burden and costs of responding to the data requests and any document requests will depend on the number of identified drug products. The draft requests indicate that the identified drug products could include all brand name drugs that have faced any generic drug competition.[40] They would cover not only brand drug "products that have first faced generic competition since January 1, 1999" but also products "that have received notice of the filing of an ANDA."[41] This increases the number of products significantly because it can take years for a generic drug for which an ANDA has been filed to actually compete with a brand name drug in the marketplace.

In these circumstances, the requests easily could include hundreds of brand name drug products. To conduct a robust empirical study, the FTC need not include 100% of the relevant

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[40] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 4, Mar. 29, 2006, www.ftc.gov.

[41] *Id.* at 5.

brand name drug products from this time period. It can reduce the compliance burden significantly by using a stratified random sample, a well-accepted sampling methodology for empirical studies.[42]

The brand name drug products can be stratified or grouped based on revenues for a relevant time period, such as the average annual revenues for a three-year period preceding generic entry. The FTC then can group the products based on a range of revenues such as over $2 billion in sales, $1.5-2 billion in sales, $1-1.5 billion, $500 million to $1 billion, and less than $500 million. Instead of using 100% of the products, the FTC can select a smaller random sample, such as 20-25% of the products from each of these groups. This will eliminate any potential biases associated with the total sales of the drug products in the sample (such as too many products with relatively small sales or too many with relatively large sales). The FTC would need only IMS revenue data by drug product to select the sample before issuing the special orders that identify the drug products.

Without use of a sampling approach, the FTC would have to study hundreds of drug products for which there are no authorized generics. The sampling process should be aimed at reducing the number of such drug products (that is, those without an authorized generics) while including those products for which companies have issued authorized generics.

As the FTC estimates show, the burden and cost on companies of complying with the special orders depends directly on the number of identified drug products.[43] Thus, the use of a stratified random sample would be a big step in reducing the burden and cost of the study.

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[42] S. L. Lohr, Sampling: Design and Analysis, Duxbury Press, 1999; W. G. Cochran, Sampling Techniques, 3rd ed., Wiley, 1977; Hansen et al., Sample Survey Methods and Theory, Wiley, 1953.

[43] FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062105, at 12, Mar. 29, 2006, www.ftc.gov.

VIII. ADDITIONAL INFORMATION FROM GENERIC DRUG COMPANIES MAY ADVANCE THE ENTRY ANALYSIS

A core purpose of the study is to evaluate empirically whether authorized generics have deterred generic entry. For this entry analysis, data from generic drug companies on the costs and profitability of entry by them is fundamental. This analysis should place weight on how generic drug companies analyze the costs of entry and the return on investment. To ensure that the FTC receives the key information for this entry analysis, PhRMA recommends the following revisions to the Paragraph IV generic drug company requests:

Suggested Changes	Reasons for Changes
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, and 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, (c) whether the company's sales of the product will result or has resulted in additional sales in other products (this includes additional sales as a result of having a fuller line or larger portfolio of products), and/or (de) 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.	• More in depth analysis of the profitability of generic entry • Better data on the return on investment associated with entry • Need for entry data that includes impact on other products • Better data on the financing of litigation costs

b. data ~~sufficient to~~ showing the identified product's development costs, costs to file ANDA, and patent-related litigation costs or financing (including data or other information on contingency arrangements or other fee structures). c. data showing the identified product's return on investment during (a) any 180-day marketing exclusivity period and (b) after that period. This includes data accounting for increased sales of additional products (e.g., data associated with greater sales from having a full line or portfolio of products).	

These modifications will ensure that the FTC's study is predicated on the generic companies' data on entry costs and return on investment. It will ensure that the FTC accounts for the return on investment that generic companies enjoy beyond any marketing exclusivity period and for related products. We expect the return on investment data will conclusively refute any concerns that the introduction of low priced authorized generics has made entry by others financially unviable.

CONCLUSION

PhRMA respectfully requests that the FTC consider these comments before serving any special orders. For the foregoing reasons, the FTC should modify the proposed information requests to reduce the burden while enabling it to conduct a robust empirical study of authorized generic competition.