Center for Regulatory Effectiveness

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December 18, 2000

Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Generic Drug Study–FTC File No. V000014

Dear Sir or Madam:

Attached please find comments by the Center for Regulatory Effectiveness on the FTC's Proposed Collection of Information regarding the Hatch-Waxman Act, 65 Fed. Reg. 61334 (October 17, 2000). CRE's comments address a number of issues, but we wish to emphasize one important point in this cover letter.

In order for the public to exercise its right to comment on whether the information is necessary for the proper performance of the FTC's functions, the Paperwork Reduction Act ("PRA") requires that the public be provided with the Commission's planned methodology for using the requested information to achieve the Commission's "proper functions." Furthermore, the Commission is required by the PRA to have a plan for the use of the data. 44 U.S.C. §§ 3506(c)(3)(H); 506(c)(1)(A)(vi).

The *Federal Register* notice for this proposed collection of information does not provide the FTC's planned methodology or plan for using the requested information. Nowhere does it explain with any specificity how the FTC will use the information to determine whether anti-competitive activity is occurring. In order to comply with the PRA, the FTC must explain what its enforcement standard is in this context, and how the sought information will be used to determine compliance with that standard. Otherwise, the public will be denied its right guaranteed by the PRA to comment on these issues.

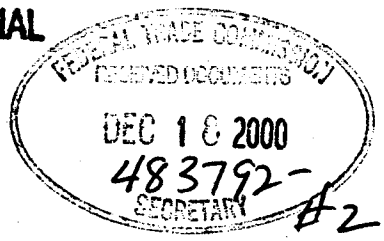
This statutorily required information is not provided by the FTC's current *Federal Register* notice. Consequently, in order to comply with the PRA, the statutorily required information must be included in the package that the FTC sends to OMB for review and approval. The FTC's submission to OMB must include a specific discussion of how the FTC will use the requested information to determine whether the agreements at issue are improper, even if they comply with the Hatch-Waxman Act and the FDA's implementing rules. The public has the right to notice of and an opportunity to comment on the FTC's submission to OMB. 44 U.S.C. § 3507 (a)(1)(D); 5 C.F.R. §§ 1320.8(d)(1); 1320.11(a).

Sincerely,

Jim J. Tozzi
Member, CRE Board of Advisors

Attachment

ORIGINAL



THE CRE REPORT CARD
ON
THE FTC'S PROPOSED COLLECTION OF INFORMATION REGARDING THE HATCH-WAXMAN ACT

Generic Drug Study - FTC File No. V000014

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THE CRE REPORT CARD ON THE FTC'S PROPOSED COLLECTION OF INFORMATION REGARDING THE HATCH-WAXMAN ACT GENERIC DRUG STUDY - FTC FILE NO. V0000414

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CRE's REPORT CARD FOR THE FTC'S PROPOSED INFORMATION COLLECTION REQUEST ON THE HATCH-WAXMAN ACT

Requirement			
Paperwork Reduction Act		**Basis Established/Issue Adequacy Addressed**	**Basis Not Established/Issue Not Adequately Addressed**
1.	Adequacy of Notice and Opportunity to Submit Comments to OMB		X
2.	Purpose, Need and "Practical Utility" Requirements		X
3.	Accuracy of Burden Estimates		X
4.	Preparedness of Designated Agency Office to Process the Information to Be Collected; Plan for Effective and Efficient Management of the Information		X
5.	Testing of Proposed Information Collection		X
6.	Duplicativeness with Information Otherwise Available to the Agency		X
7.	Understandability of Paperwork Requirements		X
8.	Implementation Consistent and Compatible with Existing Requirements	To Be Determined	To Be Determined
9.	Duration of Record Retention Period	X	
10.	Allowance of Reduced or Alternate Requirements for Small Businesses		X
11.	Use of Information Technology to Reduce Burden	X	
12.	Consideration of, and Certification Regarding, Public Comments on Items 2-11	To Be Determined	To Be Determined

THE CRE REPORT CARD
ON
THE FTC'S PROPOSED COLLECTION OF INFORMATION REGARDING THE HATCH-WAXMAN ACT
GENERIC DRUG STUDY - FTC FILE NO. V0000414

I. Introduction

The Center for Regulatory Effectiveness submits these comments on the Federal Trade Commission's notice of its proposed collection of information published at 65 Fed. Reg. 61334 (October 17, 2000). The FTC explained in its *Federal Register* notice that it,

> *is considering a study to investigate how generic drug competition has developed in light of certain provisions of the Hatch-Waxman Act that govern entry of generic drug products. Before investigating whether these provisions of the Hatch-Waxman act encourage generic competition or facilitate the use of anti-competitive strategies, the FTC seeks public comments on its proposed information requests to firms in the pharmaceutical drug industry. Comments will be considered before the FTC submits a request for Office of Management and Budget (OMB) review under the Paperwork Reduction Act.*

Id.

CRE's comments are submitted in the form of a "Report Card" scoring the proposed information collection request's ("ICR") compliance with the requirements of the Paperwork Reduction Act ("PRA"). The Report Card delineates instances of compliance and non-compliance with the requirements of the PRA. At the onset, however, CRE emphasizes two very important points:

1. *The ICR is impermissible under the PRA because the ICR is not necessary for the proper performance of the FTC's functions and has no practical utility*, 44 U.S.C. § 3506(c)(2)(A)(i), (c)(3)(A); and

2. *The ICR is impermissible under the PRA because the FTC has not provided public notice and an opportunity to comment on the FTC's proposed plan and methodology for using the requested information*, 44 U.S.C. §§ 3506(c)(3)(H); 506(c)(1)(A)(vi).

In regard to the first point, the FTC's ICR seeks information as to the potentially anti-competitive effects of a regulatory regime that is in a state of flux. The Hatch-Waxman Act is implemented by regulations promulgated by the Food and Drug Administration ("FDA"). Some of those regulations have been set aside by recent court decisions. E.g., Teva Pharmaceuticals, USA, Inc. v. FDA, 182 F. 3d 1003 (D.C. Cir. 1999); Mova Pharmaceutical Corp. v. Shalala, 140 F. 3d 1060 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, 139 F. 3D 889 (4th Cir. 1998). The FDA has proposed new regulations under the Hatch-Waxman Act. 64 Fed. Reg. 42873 (Aug. 6, 1999). The stated goals of these proposed new rules are to address the adverse court decisions and to resolve competition-related issues that are the subject of the FTC's ICR. Id. at 42874-85.

The FTC itself filed comments on the proposed new FDA rules. The FTC's comments correctly noted that "the Proposed Rule is designed to address problems that have arisen with generic and branded companies entering into certain types of agreements that result in hindering, rather than speeding, generic competition" (Exhibit A, p. 1). The FTC's comments further note "that the Proposed Rule to clarify the circumstances in which applicants may obtain a 180-day exclusive marketing period may remedy the delayed generic competition that has resulted from certain types of agreements between generic and innovator companies." (Exhibit A, p. 2).

Under these circumstances, and given the FTC's stated purposes for its ICR, collecting information now regarding a regulatory scheme that is still evolving and completely within the legal jurisdiction of another agency would (1) have no practical utility and (2) is not necessary to the FTC's proper functions, both of which result in non-compliance with the PRA. Furthermore, the FTC has failed to comply with a

number of mandatory PRA requirements distinct from the practical utility/necessity issue, such as failing to provide a specific objective estimate of burden.

Congress has delegated responsibility for implementing the Hatch-Waxman Act to the FDA, not the FTC. The FTC should wait until the FDA promulgates final new rules under the Hatch-Waxman Act and then determine whether any ICR or investigation of this issue is necessary.

In regard to the second point, in order for the public to exercise its right to comment on whether the information is necessary for the proper performance of the FTC's functions, the PRA requires that the public be provided with the FTC's planned methodology for using the information to achieve the FTC's "proper functions." Furthermore, the FTC is required by the PRA to have a plan for the use of the data. 44 U.S.C. §§ 3506(c)(3)(H); 506(c)(1)(A)(vi).

The *Federal Register* notice for the proposed collection of information does not provide the FTC's planned methodology or plan for using the requested information. Nowhere does it explain with any specificity how the FTC will use the information to determine whether anti-competitive activity is occurring. In order to comply with the PRA, the FTC must explain what its enforcement standard is in this context, and how the sought information will be used to determine compliance with that standard. Otherwise, the public will be denied its right guaranteed by the PRA to comment on these issues.

The statutorily required information is not provided by the FTC's current *Federal Register* notice. Consequently, in order to comply with the PRA, it must be included in the package that the FTC sends to OMB for review and approval under the PRA. In order to comply with the PRA, the FTC's submission to OMB must include a specific discussion of how the FTC will use the requested information to determine whether the agreements at issue are illegal, even if they comply with the Hatch-Waxman Act and the FDA's implementing rules. And the public has the right to notice of and an opportunity to comment on the FTC's submission to OMB. 44 U.S.C. § 3507(a)(1)(D); 5 C.F.R. §§ 1320.8(d)(1); 1320.11(a).

II. Comments Accompanying CRE's Report Card on The FTC's Proposed Information Request of the Hatch-Waxman Act

1. Adequacy of Notice and Opportunity to Submit Comments to OMB

REQUIREMENT: Under the Paperwork Reduction Act, 44 U.S.C. §§ 3501, *et seq.*, an agency must obtain OMB's approval before imposing record keeping or reporting requirements (referred to as "information collection requirements") on the public. The notice must provide the public with a minimum of 60 days within which to submit comments to the appropriate "desk officer" at OMB. See 44 U.S.C. § 3507 (a)(1)(D); 5 C.F.R. §§ 1320.8(d)(1), 1320.11(a).

COMPLIANCE/NONCOMPLIANCE:

The FTC has solicited public comment on its proposed ICR. However, the public has not been provided an adequate opportunity to comment for the reasons stated in Items 2 and 4 below. Moreover, to ensure full compliance, OMB will need to establish a second round of comments on any actual materials submitted by FTC to OMB.

SUGGESTED REMEDIAL ACTION:

FTC must provide the public with the information described in Items 2 and 4 below so that they can comment on the FTC's compliance with the PRA's requirements. Moreover, OMB is obliged to carry out the second comment period.

2. Purpose, Need and "Practical Utility" Requirements

REQUIREMENT: Before imposing a paperwork requirement on the public, the sponsoring agency must demonstrate that "the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility." 44 U.S.C. § 3506(c)(2)(A)(i), (c)(3)(A). "Practical utility" is defined as "the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's

ability to process the information it collects...in a useful and timely fashion." 5 C.F.R. §1320.(*l*). Moreover, a proposed information collection should be approved only if it would "enhance the quality, utility, and clarity of the information to be collected." 44 U.S.C. § 3506(c)(2)(A)(iii).

COMPLIANCE/NONCOMPLIANCE:

The proposed ICR notice states that the purpose of the information collection is to investigate whether, "[P]rovisions of the Hatch-Waxman Act encourage generic competition or facilitate the use of anticompetitive strategies..." The NPRM also indicates that the information would be used to assess whether certain strategies or actions may merit law enforcement action.

To facilitate their goals, the Commission has requested very broad categories of information, such as "[A]ll studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) (or in the case of unincorporated entities, individuals exercising similar functions)" which may have been prepared in support of certain possible agreements. However, the FTC's proposed request for information fails to adhere to the requirements of the PRA for two key reasons:

a. **No model provided to the public on how information would be used to meet the Commission's stated goals.**

In order for the public to comment on whether the information is necessary for the proper performance of agency functions, it is essential that the public be provided with the agency's planned methodology for using the requested information to achieve the Commission's "proper functions" goal. Furthermore, the Commission is required by the Act to have such a plan for the use of the data. 44 U.S.C. §§3506(c)(3)(H); 3506(c)(1)(A)(vi).

By failing to make public the methodology for how the information will be used, the Commission is depriving the public of their right to comment on whether the information is necessary

for the FTC's proper functioning, including the right to comment on whether the data would have practical utility.

b. The FDA regulatory regime implementing the Hatch-Waxman Act has: 1) changed; and 2) is not final

The FTC has indicated that they want to request information from pharmaceutical companies primarily to assess whether the Hatch-Waxman Act has resulted in agreements/strategies which may delay generic drug competition. However, significant portions of the FDA's implementing regulations – which govern any such agreements – were invalidated by a series of court decisions. E.g., Teva, 182 F.3d 1003; Mova, 140 F.3d 1060; Granutec, 139, F.3d 889. The FDA has responded to this situation by: 1) issuing interim final rules; and 2) initiative a rulemaking to develop new implementing regulations.

Since: 1) much of the historical data requested by the FDA would correspond to a defunct regulatory regime; 2) the FDA has not finalized the regulations by which the Hatch-Waxman Act will be implemented; and 3) the FTC has formally indicated in its comments to FDA on proposed revisions that such revisions may well assuage FTC concerns (Exhibit A, p. 2), it is not possible for the requested information to answer FTC questions about either the impact of the legislation or the state of competition . Therefore, the information has no practical utility.

SUGGESTED REMEDIAL ACTION:

1. The Commission needs to publish for public comment the methodology by which the desired information would be used to achieve the goals delineated in the *Federal Register* notice. The model should include an explanation of how each information item sought through the proposed ICR:

   - Would be used by the agency; and

- Why each information item is necessary for the proper functioning of the agency's investigative methodology.

2. The FTC needs to at least postpone any ICR on this issue until the FDA promulgates final new rules. If the FTC then still believes an ICR on this issue is necessary, then it should revise the planned ICR to demonstrate the actual rather than speculative need for the information. Furthermore, the FTC needs to request public comment on the revised ICR.

3. Prior to issuing an ICR, the Commission needs to:

   - Wait until the FDA establishes the regulatory regime for the Hatch-Waxman Act; and

   - Assess whether the revised regulations meet Commission concerns.

3. Accuracy of Burden Estimates

REQUIREMENT: The "sponsoring agency" is required to "evaluate the accuracy of the agency's estimate of the burden of the proposed information to be collected." 44 U.S.C. § 3506(c)(2)(A)(ii). OMB's ongoing and consistent practice is to require sponsoring agencies to submit *accurate* estimates of burden. When a sponsoring agency's burden estimate is demonstrably and materially inaccurate, *e.g.*, due to the failure to assess whole categories of burden, OMB's practice is to return the "clearance package" containing the proposed paperwork requirements to the sponsoring agency, and to require the agency to resubmit the clearance package with corrected burden estimates. The reason for this practice is that OMB cannot make key determinations without possessing accurate burden data. For example, without accurate data, OMB cannot determine whether the paperwork burdens to be imposed on respondents are justified based on the benefits to be provided by the information to be collected by the agency.

COMPLIANCE/NONCOMPLIANCE:

The FTC is required by the PRA, 44 U.S.C. § 3506 (c)(1)(A)(iv), to provide a "specific, objectively supported estimate of burden." The FTC has not complied with the requirement to provide the mandated specific, objective estimate. Such an estimate may not even be possible for the proposed ICR because the FTC has not quantified the volume of the information requested. For example, the FTC has not provided an objectively supported estimate of the number of documents being requested nor of the size of such documents nor of the number of locations around the world such documents may be stored in nor of the number of individuals within each company who would have to search for such documents.

The "Estimated Burden Hours" section of the *Federal Register* notice recognizes the vagueness of the information request by providing a ten-fold range (15-150 hours) for identifying requested information. Furthermore, the FTC provides absolutely no support, let alone objective support, for its burden estimate.

It is important to note that the requirement for a "specific, objectively supported estimate of burden" is not a minor element of the Act but is essential to the very purpose of the PRA. Specifically, through the PRA, Congress forbade agencies from undertaking broad "fishing expeditions" of the type used in discovery proceedings.

It is also important to note that the onus is on the requesting agency to develop the "specific, objectively supported estimate of burden." Industry, in their comments on a proposed ICR, have no responsibility to provide the information needed to develop the specific burden estimate.

Finally, the public has been denied its right to comment on the FTC's burden estimates because the FTC has not provided the public with the basis for its burden estimates.

SUGGESTED REMEDIAL ACTION:

The agency needs to provide for public comment, a specific, objectively supported estimate of the burden that the proposed information collection request would impose on the private sector. If the FTC cannot provide such an estimate, then it cannot conduct the proposed ICR.

4. **Preparedness of Designated Agency Office to Process the Information to Be Collected; Plan for Effective and Efficient Management of the Information**

REQUIREMENT: The agency must certify to OMB that the proposed information collection requirement "has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public." 44 U.S.C. § 3506(c)(3)(H). Moreover, prior to submitting the proposed information collection to OMB, the agency is required to have established "a plan for the efficient and effective management and use of the information to be collected, including necessary resources." Id. § 3506(c)(1)(A)(vi).

COMPLIANCE/NONCOMPLIANCE:

The Commission is required to have a plan for the management and use of the information to be collected through the proposed ICR. It is incumbent on the FTC to make such a plan public in order for that the public is not deprived of their right to comment on the necessity and practical utility of the information collection. Furthermore, without such a public release and explanation of the data plan, it is not possible for the public to know whether the agency has a plan which complies with the requirements of 44 U.S.C. § 3506(c)(3)(H). Thus, the agency has not demonstrated compliance with this requirement

The Commission is also required to have allocated the resources necessary for the efficient and effective management and processing of the requested information. Not only has the agency not demonstrated to the public that they

have allocated the necessary resources but also, given the Commission has not quantified the amount of data to be processed, it does not appear even theoretically possible for the Commission to have allocated the necessary resources as required by the Act.

SUGGESTED REMEDIAL ACTION:

The FTC should present for public comment:

1. The Commission's plan for the efficient and effective management and use of the information the FTC proposes to collect; and

2. The budgetary information demonstrating that the Commission has allocated sufficient resources to accomplish #1.

If the FTC attempts to comply with this PRA requirement by submitting its plan to OMB, then that plan must be made available for public comment at the time it is sent to OMB or earlier.

5. Testing of Proposed Information Collection

REQUIREMENT: The agency must "review each collection of information before submission to the Director [i.e., of OMB] for review under this chapter, including...(V) a test of the collection of information through a pilot program, if appropriate." 44 U.S.C. § 3506(c)(1)(A)(v).

COMPLIANCE/NONCOMPLIANCE:

If the FTC has complied with this PRA requirement, then it has not explained how in the notice of its proposed ICR. If the FTC believes that a pilot program is inapplicable, then it has not explained why in the proposed ICR.

SUGGESTED REMEDIAL ACTION:

If the FTC has already conducted a pilot program, then it needs to describe that program. If the FTC believes that a pilot program is inapplicable, then it needs to explain why. Otherwise, the FTC should perform a pilot program before it conducts the proposed ICR.

6. **Duplicativeness with Information Otherwise Available to the Agency**

REQUIREMENT: The agency must certify to OMB that, based on public comments received, the proposed information collection "is not unnecessarily duplicative of information otherwise reasonably accessible to the agency." 44 U.S.C. § 3506(c)(3)(B).

COMPLIANCE/NONCOMPLIANCE:

The FTC has not complied with this requirement because:

i) significant portions of the information requested are reasonably available to FTC from public sources; and

ii) the Congressional Budget Office has already analyzed the impact on competition and pharmaceutical prices resulting from the Hatch-Waxman Act.

Some of the data to be requested in the FTC's proposed information collection are already reasonably available to the FTC from public source such as other federal agencies. For example, the FDA's *Orange Book* contains some of the information sought by the ICR. The FDA's new rules may also provide the FTC with some of this information (Exhibit A, at p. 2).

The Congressional Budget Office has already analyzed the issue that FTC claims as the primary justification for the proposed ICR, assessing how the Hatch-Waxman Act has affected competition from generic drugs in the pharmaceutical industry. Specifically, in July 1998, the Congressional Budget Office published a study, *How Increased Competition from Generic Drugs Has*

Affected Prices and Returns in the Pharmaceutical Industry." Chapter Four of this study is titled "The Effects of the Hatch-Waxman Act on the Returns from Innovation." This government study determined that, "The Hatch-Waxman Act helped increase the supply of generic drugs by lowering the cost of getting them approved by the Food and Drug Administration." The study also found that the patent extensions contained in the Hatch-Waxman Act, "did not completely protect the returns of brand name manufacturers from the dramatic rise in the marketshare for generic drugs."

Although the existence of a previous federal study on the competitive impact resulting from the Hatch-Waxman Act does not, in and of itself, prevent the FTC from studying the issue, the FTC's failure to discuss the sufficiency of this study in the *Federal Register* notice demonstrates that the Commission has not considered using reasonably available sources of information before requesting permission for an ICR.

The FTC is not the only agency addressing the issue of whether the 180-day exclusivity period may impede competition. As the FTC acknowledges, the FDA is also addressing this issue in its Hatch-Waxman Act rule making. 64 Fed. Reg. 42873, 42874-85; Exhibit A. p. 2. Much of the information sought by the FTC's proposed ICR should be available from the FDA rule making record.

Failure of the FTC to utilize reasonably available information, whether from the FDA, Patent Office, CBO, etc., prior to seeking to collect information from the private sector is a violation of the PRA.

SUGGESTED REMEDIAL ACTION:

The FTC needs to determine what potentially relevant information it seeks is available from public sources including, but not limited to, federal agencies, Congress, and academia. The FTC is required, by the PRA, to reshape and present for public comment, its proposed Information Collection Request to exclude information which can be reasonably obtained from other sources.

7. Understandability

REQUIREMENT: The agency must certify to OMB that, based on the public comments received, the proposed information collection "is written using plain, coherent, and unambiguous terminology *and* is understandable to those who are to respond." 44 U.S.C. § 3506(c)(3)(D). [emphasis added]

COMPLIANCE/NONCOMPLIANCE:

Although much of the language in the proposed ICR is understandable, certain elements of the proposed information collection are ambiguous. For example, the proposed ICR asks for "all studies, surveys analyses and reports...that evaluate or analyze the reasons for making such agreement..." Is the FTC seeking disclosure of trade secret, attorney-client privileged, or otherwise confidential information? If so, then the FTC must explain its authority to obtain such information and, assuming arguendo that the FTC has any such authority, how it intends to preserve its confidentiality, especially in light of the possibility that the information sought by the FTC could possibly lead to litigation or enforcement actions.

SUGGESTED REMEDIAL ACTION:

The FTC needs to reword the ICR so as to clearly explain how it pertains to trade secret or otherwise confidential information, and how that information will be protected from disclosure. The FTC needs to reword the ICR to clearly state that it does not require disclosure of attorney-client or attorney-work-product privileged information.

8. Implementation Consistent and Compatible with Existing Requirements

REQUIREMENT: The agency must certify to OMB that, based on the public comments received, the proposed information collection "is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond." 44 U.S.C. § 3506(c)(3)(E).

COMPLIANCE/NONCOMPLIANCE:

Until public comments are received and the FTC responds to them, the ICR's compliance with this PRA requirement cannot be graded.

SUGGESTED REMEDIAL ACTION:

None yet.

9. **Duration of Record Retention Period**

REQUIREMENT: The agency must indicate "for each recordkeeping requirement the length of time persons are required to maintain the records specified." 44 U.S.C. § 3506(c)(3)(F).

COMPLIANCE/NONCOMPLIANCE:

No recordkeeping requirements are associated with the proposed ICR. The proposed ICR clearly states what the relevant time frame for the proposed ICR.

SUGGESTED REMEDIAL ACTION:

None.

10. **Allowance of Reduced or Alternate Requirements for Small Businesses**

REQUIREMENT: The agency must sign a certification to OMB stating that the proposed paperwork requirements "reduce[] to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities...(i) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;...and (iii) an exemption from coverage of the collection of information, or any part thereof." 44 U.S.C. § 3506(c)(2)(C).

COMPLIANCE/NONCOMPLIANCE:

The FTC has completely failed to: 1) acknowledge that many of the potential respondents, particularly among generic drug companies, may be small businesses; and 2) minimize the paperwork burden on these small companies.

Pharmaceutical preparation manufacturing, according to the North American Industry Classification System (NAICS) is code 325412. This NAICS designation replaces SIC codes in SBA regulations. The SBA definition of a small business size standard for pharmaceutical industry, effective October 1, 2000, is 750 employees.

In an apparent direct contravention to the requirement to minimize the burden on small businesses, the proposed ICR has more questions for generic drug companies than for innovator companies.

SUGGESTED REMEDIAL ACTION:

The FTC needs to: 1) Determine and present for public comment the number of respondents which would be small business (according to SBA definition); and 2) set alternative compliance requirements for small business to minimize the burden on these firms.

11. Use of Information Technology to *Reduce* Burden

REQUIREMENT: The agency must certify to OMB that, based on the public comments received, the proposed information collection "to the maximum extent practicable, uses information technology to *reduce burden* and improve data quality, agency efficiency and responsiveness to the public." 44 U.S.C. § 3506(c)(2)(I) [emphasis added].

COMPLIANCE/NONCOMPLIANCE:

The FTC adequately considered the use of technology in the proposed ICR.

SUGGESTED REMEDIAL ACTION:

None.

12. **Consideration of, and Certification Regarding, Public Comments on Items 2-11**

REQUIREMENT: The agency is required to "certify (and provide a record supporting such certification, including public comments received by the agency) that each collection of information submitted to the Director" of OMB complies with the ten specified standards set forth at section 3506(c)(3). (44 U.S.C. § 3506(c)(3)).

COMPLIANCE/NONCOMPLIANCE:

To Be Determined.

SUGGESTED REMEDIAL ACTION:

None yet.

EXHIBIT A

Comment of the Staff of the Bureau of Competition and of Policy Planning
of the Federal Trade Commission
Before the Food and Drug Administration
In the Matter of
180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications
Docket No. 85N-0214

Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

In the Matter of

180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications

Docket No. 85N-0214

COMMENT OF THE STAFF OF THE BUREAU OF COMPETITION AND OF POLICY PLANNING OF THE FEDERAL TRADE COMMISSION

November 4, 1999*

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*Inquiries regarding this Comment should be directed to Michael Wroblewski (202) 326-2155

I. The FTC's Interest in this Proceeding.

The staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission (FTC) welcomes this opportunity to present its views on important competition issues raised in the above-captioned proceeding.[1] In this proceeding, the Food and Drug Administration (FDA) has issued a Proposed Rule with the purpose of clarifying existing eligibility requirements for abbreviated new drug application (ANDA) applicants and remedying its rules in light of recent court decisions invalidating portions of FDA's current regulations.[2] The FDA intends that the Proposed Rule will permit the prompt entry of generic drug products into the market while maintaining the incentive of marketing exclusivity for generic drug manufacturers.[3] In particular, the Proposed Rule is designed to address problems that have arisen with generic and branded[4] companies entering into certain types of agreements that result in hindering, rather than speeding, generic competition.[5]

The FTC is an independent administrative agency charged with promoting the efficient functioning of the marketplace by taking law enforcement action against commercial practices injurious to consumers and by increasing consumer choice by promoting vigorous competition. Staff approaches the competition issues presented in this proceeding from experience in enforcing Section 7 of the Clayton Act[6] and Section 5 of the Federal Trade Commission Act[7] and from antitrust enforcement activities affecting the generic drug industry.[8] The staff of the FTC's Bureau of Economics has recently released a report studying the competition issues in the pharmaceutical industry, which also informs this view.[9]

Briefly, this comment notes the competitive benefits of lower prices and greater innovation

that the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) has spurred in the pharmaceutical industry by streamlining the approval process for generic drug products. The comment notes that the Proposed Rule to clarify the circumstances in which applicants may obtain a 180-day exclusive marketing period may remedy the delayed generic competition that has resulted from certain types of agreements between generic and innovator companies. The FTC recently has initiated several investigations of agreements between branded companies and their generic counterparts that may have the effect of forestalling generic competition. The comment also suggests that the FDA consider a requirement that both patent litigation settlement agreements (either full or partial settlements) between branded companies and ANDA applicants and agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the agency in a timely manner and be accessible to the federal antitrust authorities on a non-public basis so that the antitrust agencies will be aware of any possible anticompetitive issues involved with such settlements.

II. Background.

In 1984, Congress enacted the Hatch-Waxman Act to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. The Hatch-Waxman Act specifies in detail the required contents of an ANDA. Under the Hatch-Waxman Act, for each patent listed in the Orange Book[(10)] for the relevant branded drug, an ANDA applicant must certify one of the following claims: (1) that such patent information has not been filed; (2) that such patent has expired; (3) that the proposed drug will not be marketed until expiration of the patent; or (4) that either the proposed generic drug does not infringe the patent or the patent is invalid.[(11)]

It is this fourth type of certification with which the FDA Proposed Rule and this comment are concerned. If an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification[(12)] and provides the patent holder with a 45-day window, during which it may bring suit against the applicant.[(13)] If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of (1) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (2) the issuance of a non-appealable court decision finding the patent invalid or not infringed. This allows the patent holder time to enforce its patent in court before the generic competitor is allowed to enter the market.

Often more than one company will file an ANDA that includes a paragraph IV certification because these companies also seek to provide generic competition to a particular branded drug. However, the Hatch-Waxman Act provides that such subsequent ANDA applications will not be approved until 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. Thus, the Hatch-Waxman Act effectively grants the first-filed ANDA holder 180 days of marketing exclusivity. As the FDA notes, "[t]he award of a 180-day period of market exclusivity for certain ANDA applicants with paragraph IV certifications was designed to maintain [a] balance by rewarding generic firms for their willingness to challenge unenforceable and invalid innovator patents, or design noninfringing drug products."[(14)]

In implementing this provision in the past, the FDA added a requirement that the first

ANDA applicant must have "successfully defended against a suit for patent infringement" before the applicant is eligible for the 180-day marketing exclusivity period. Two recent court of appeals decisions, however, held that the FDA had exceeded its statutory authority in imposing the "successful-defense requirement" as a prerequisite to obtaining the 180-day marketing exclusivity.(15)

In this proceeding, the FDA proposes new rules implementing the 180-day marketing exclusivity provision and clarifies which applicants are eligible for the marketing exclusivity. The Proposed Rule is designed to address the FDA's expressed concern that, "[u]nder current regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company."(16) Such agreements may have the effect of forestalling the triggering of the 180-day period and may, therefore, bar other generic firms from entering the market even when their products would not infringe a valid patent.(17) In such circumstances, the FDA is barred from providing final approval for all subsequent ANDA applicants and, thus, generic competition is precluded from occurring.

The FDA has proposed to amend its rules by placing a time limit (180 days) on when the first-filed ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period and by clarifying which applicants are eligible for the 180-day marketing exclusivity.

III. Consumers Have Benefitted from the Hatch-Waxman Act.

Since the enactment of the Hatch-Waxman Act, American consumers have had greater access to generic drugs at lower prices than their branded counterparts. Indeed, the generic drug share of prescription drug volume has increased by almost 150 percent since enactment of the Hatch-Waxman Act in 1984.(18) Empirical research has shown that relaxation of entry impediments has given rise to significant entry and price competition in drug markets.(19)

Total generic drug market share has increased as well in the years since the Hatch-Waxman Act passed. According to a recent report by the Congressional Budget Office (CBO), sales of generic drugs increased from 19 percent of U.S. prescription sales in 1983 to over 40 percent in 1995.(20) The industry has also seen an increase in the percent of branded drugs that have a generic competitor on the market. Today, nearly 100 percent of the top-selling drugs with expired patents have generic versions available, versus only 36 percent in 1983.(21)

In addition, evidence from the CBO Study indicates that for many branded drugs whose patents have recently expired, generic copies quickly gain a large share of the market. For example, with regard to 21 innovator drugs whose first generic competitors entered the market between 1991 and 1993, the CBO Study determined that during the first full calender year in which those 21 drugs faced generic competition, generic drug products already accounted for an average of 44 percent of prescriptions dispensed through pharmacies.(22) Consumers have saved billions of dollars by purchasing these generic drugs in place of their more expensive branded counterparts. In turn, insurance and pharmaceutical

benefits management companies have positively responded to the increased availability of generic drugs by contracting with generic manufacturers for bulk purchases. Enrollees benefit from these relationships through cost savings realized via multi-tiered drug co-payment structures. Finally, in response to generic competition, innovator companies research, develop, and market increasing numbers of improved new drugs. Such additions to the marketplace may satisfy previously unmet medical needs, break new therapeutic ground or compete with older drugs.

Moreover, the Hatch-Waxman Act has helped to expand the number of generic drug manufacturers producing the same drug. This increased breadth and depth of generic drug market presence has augmented pharmaceutical competition on three levels: brand-brand, brand-generic, and generic-generic. The benefits of this increased competition have been confirmed in FTC staff investigations of the pharmaceutical industry. Generally, the staff has found that the more generic versions of the same drug product that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the drug product. For example, the entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded drug product's price. Three or more companies offering a generic version of a listed drug can lower the price by at least fifty percent, if not substantially more, from the branded price. These price discounts tend to show that the sooner more companies offer the same generic product, the greater the price competition and the lower price consumers pay for a generic version of a drug product.

IV. The "Triggering Period" Proposed by the FDA Would Assist in Ensuring that Generic Competition Is Not Delayed.

The FDA has proposed to implement a "use it or lose it" triggering period in which first-filed paragraph IV ANDA applicants have 180 days to start (or "trigger") the 180-day marketing exclusivity period. The triggering period would begin after a second generic drug application with a paragraph IV certification has received tentative approval. During the triggering period, the first-filed ANDA applicant would be required either to obtain a final court decision finding the patent to be invalid, unenforceable, or not infringed by the ANDA product or to begin commercial marketing of the generic drug. In three instances, the triggering period will start not only after a subsequent ANDA receives tentative approval but also after, depending upon the circumstance, (1) the 30-month stay of ANDA approval has expired if the first-filed ANDA applicant is involved in patent litigation; (2) a preliminary injunction prohibiting the marketing of an ANDA product (if a court has issued one) has expired; or (3) where applicable, the statutorily described exclusivity period for the listed drug has expired.

A "use-it-or-lose-it" triggering period appears to be helpful in implementing the Hatch-Waxman Act's intent to "make available more low cost generic drugs."[23] The 180-day time period appears more than adequate to permit the applicant to prepare to launch the generic product; as the FDA noted in the Proposed Rule, generic drug products are "routinely marketed within a 2-month period following ANDA approval."[24] In addition, the *Mova* court indicated that the FDA could prescribe a period within which a first ANDA applicant must bring its product to market in order to benefit from the 180-day marketing exclusivity period.[25] Moreover, such an obligation does not absolutely require the first-filed ANDA applicant to begin commercial marketing, but only to begin commercial marketing or obtain a final court order if it seeks to obtain the 180 days of marketing

exclusivity.

In practical effect, the "use-it-or-lose-it" triggering period ensures that, once there is another generic product that has received tentative approval from the FDA -- and, where applicable, the other relevant statutory or court-ordered time periods have expired[26] -- the first-filing ANDA applicant must fish or cut bait, *i.e.*, it must either move to commercial marketing or a final court order within 180 days or lose the 180-day marketing exclusivity. Either way, the FDA's proposed triggering rule ensures that the ongoing potential for generic competition is maintained so that consumers may benefit by a ready supply of generic versions of a drug product. By adding another triggering event -- tentative approval for a second generic drug -- that is not within the control of either the first-filing ANDA applicant or the branded company, the Proposed Rule would reduce the ability and incentive of generic and branded companies to enter into agreements that can forestall generic competition.

V. The FDA's Proposal to Limit 180-Day Marketing Exclusivity to the First ANDA Applicant Is Preferable to Rolling Eligibility.

The FDA has proposed to continue its current approach that only the first substantially complete ANDA for a listed drug with a paragraph IV certification would be eligible for exclusivity. No other ANDA applicant with a paragraph IV certification will be eligible for the 180-day marketing exclusivity for that drug product, even if the first ANDA applicant later loses its status as the first-filer (*e.g.*, by withdrawing or changing its application as a result of losing or settling its patent suit). The proposed policy appears to be a reasonable part of a solution to the delay of generic competition that the FDA has observed.[27]

This policy is preferable to a rolling eligibility policy in which the next-in-line ANDA applicant obtains the right to the 180-day marketing exclusivity period if the first-filing ANDA applicant loses its status as the first-filer. A rolling eligibility process might result in successive agreements between branded drug and generic companies, each of which would have the effect of forestalling competition, and thus cause indefinite delays in generic competition. Such indefinite delay could cause consumers to continue to pay significantly higher prices for prescription drugs than they would if generic competition got underway.

VI. Filing of Patent Litigation Settlement Agreements.

The FDA notes in the Proposed Rule that in order to remedy the alleged use of settlement agreements to block generic competitor entry, it prefers the triggering period approach (discussed above) over a notification approach that would require that the FDA be notified of a settlement or other agreement that alters an adversarial relationship between the first-filing ANDA applicant and either the patent owner or the NDA holder.[28] Regardless of which approach the FDA ultimately adopts, the FDA may wish to consider requiring that (1) patent litigation agreements (either full or partial settlements) between branded companies and ANDA applicants and (2) agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the agency in a timely manner and be accessible to the federal antitrust authorities on a non-public basis so that the antitrust agencies will be aware of any possible anticompetitive issues involved with such agreements.

Often the antitrust authorities are at a disadvantage in learning about a whole range of agreements involving intellectual property rights that may impede competition while

affording no countervailing competitive benefits. Indeed, the Assistant Attorney General for Antitrust has stated that "whenever there is even a more than trivial possibility of infringement, the costs of litigation skew the parties' decisions, steering them away from a serious test of the bounds of the rights of the patentee or copyright holder and towards agreements that too often make teammates out of rivals." (29)

As noted earlier, the Federal Trade Commission has initiated several investigations of agreements between branded companies and their generic counterparts. These investigations were initiated when Commission staff became aware of the agreements -- often months, and sometimes over a year, after the agreements were made. Although the Commission has the authority to seek disgorgement or restitution of ill-gotten gains from the companies,(30) consumers pay millions of dollars in higher prices during the pendency of these often-complicated investigations.

Accordingly, a system of filing with the FDA could assure better detection of anticompetitive arrangements that harm consumer welfare. If the FDA suspected the possibility of anticompetitive effects in connection with a particular agreement, it could share that agreement with the antitrust authorities pursuant to a confidentiality agreement that would protect the commercial interests of the parties to the agreement.

VII. Conclusion.

The FDA has proposed to amend its rules to implement the Hatch-Waxman Act by clarifying which applicants are eligible for the 180-day marketing exclusivity and by placing a time limit on when the first-filing ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period. Staff of the Bureau of Competition and of Policy Planning at the FTC support the FDA's proposed rule for the reasons articulated in this comment. In addition, the FDA may wish to consider a requirement that all patent litigation settlement agreements and agreements related to the filing of an ANDA application be filed with the FDA in a timely manner in order to notify the agency of possible anticompetitive issues involved with such settlements.

Respectfully submitted,

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Endnotes:

1. This comment represents the views of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, and not necessarily the views of the Commission itself or any individual Commissioner.

2. Proposed Rule, 64 Fed. Reg. 42873 (Aug. 6, 1999).

3. 64 Fed. Reg. at 42873.

4. This comment uses the term "branded" in ways synonymous with the FDA's use of the term "innovator" - that is, it refers to a patented drug or a company that has done the innovative work required to earn a patent on a drug.

5. 64 Fed. Reg. at 42882-83.

6. 15 U.S.C. § 18 (1988). Mergers subject to Section 7 are prohibited if their effect "may be substantially to lessen competition, or to tend to create a monopoly." *See, e.g.*, Hoechst AG, 120 F.T.C. 1010 (1995) (merger with Marion Merrell Dow, Inc.).

7. 15 U.S.C. § 41 et seq.

8. *See, e.g., Federal Trade Commission v. Mylan Laboratories, Inc. et al.*, 1999-2 Trade Cas. (CCH) ¶72,573 (D.D.C. 1999), *appeal filed.*

9. Staff of the Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change" (Mar. 1999) (FTC Staff Report) <http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm>.

10. The Orange Book contains a listing of all FDA-approved drug products. Any patent protection still afforded an approved drug product is also listed in the Orange Book.

11. 21 U.S.C. § 355(j)(2)(A)(vii).

12. 21 U.S.C. § 355(j)(2)(B)(i)(I).

13. 21 U.S.C. § 355(j)(5)(B)(iii).

14. 64 Fed. Reg. at 42882. The FDA's notice explains that "[t]he Hatch-Waxman Amendments benefit consumers by bringing lower priced generic versions of previously approved drugs to market, while simultaneously promoting new drug innovation through the restoration of patent life lost during regulatory proceedings." *Id.*

15. *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998); *Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998).

16. 64 Fed. Reg. at 42882.

17. Such delay could occur, for example, when the first ANDA applicant agrees not to market its product until the completion of the patent litigation so that there is neither a date at which commercial marketing has begun nor a final court decision (the two statutory triggers that start the running of the 180-day marketing exclusivity). The FDA explains:

> A necessary condition for such arrangements is that the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from 180 days of market exclusivity. Such instances are becoming more frequent because a successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic