Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the Commission on the proposed regulations. Copies of the information collection submission to OMB are available from the CFTC Clearance Officer, 1155 21st Street N.W., Washington, DC 20581, (202) 418–5160.

List of Subjects in 17 CFR Part 4

Brokers, Commodity futures.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and in particular sections 2(a)(1), 4l, 4m, 4n, 4o, and 8a, 7 U.S.C. 2, 6l, 6m, 6n, 6o, and 12(a), the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

1. The authority citation for part 4 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 6b, 6c, 6l, 6m, 6n, 6o, 12a, and 23.

2. Section 4.22 is amended by:

a. redesignating paragraphs (f)(1) introductory text, (f)(1)(i), (f)(1)(ii), (f)(1)(iii), and (f)(1)(iv) as (f)(1)(i) introductory text, (f)(1)(i)(A), (f)(1)(i)(B), (f)(1)(i)(C), and (f)(1)(i)(D);

b. redesignating paragraphs (f)(2) introductory text, (f)(2)(i), and (f)(2)(ii) as (f)(1)(ii) introductory text, (f)(1)(ii)(A), and (f)(1)(ii)(B);

c. redesignating paragraphs (f)(3) introductory text, (f)(3)(i), and (f)(3)(ii) as (f)(1)(iii) introductory text, (f)(1)(iii)(A), and (f)(1)(iii)(B); and

d. adding a new paragraph (f)(2) to read as follows:

§ 4.22 Reporting to pool participants.

* * * * *

(f) * * *

(2) In the event a commodity pool operator finds that it cannot obtain information necessary to prepare certified financial statements for a pool that it operates within the time specified in either paragraph (c) of this section or §4.7(b)(3)(i), as a result of the pool investing in another collective investment vehicle, it may claim an extension of time under the following conditions:

(i) The commodity pool operator must, within 90 calendar days of the end of the pool's fiscal year, file a notice with National Futures Association and the Commission, except as provided in paragraph (f)(2)(v) of this section.

(ii) The notice must contain the name, main business address, main telephone number and the National Futures Association registration identification number of the commodity pool operator, and name and the identification number of the commodity pool.

(iii) The notice must state the date by which the Annual Report will be distributed and filed (the ''Extended Date''), which must be no more than 150 calendar days after the end of the pool's fiscal year. The Annual Report must be distributed and filed by the Extended Date.

(iv) The notice must include representations by the commodity pool operator that:

(A) The pool for which the Annual Report is being prepared has investments in one or more collective investment vehicles (the ''Investments'');

(B) The commodity pool operator has been informed by the certified public accountant selected to audit the commodity pool's financial statements that specified information establishing the value of the Investments is necessary in order for the accountant to render an opinion on the commodity pool's financial statements. The notice must include the name of the accountant; and

(C) The information specified by the accountant cannot be obtained in sufficient time for the Annual Report to be prepared, audited, and distributed before the Extended Date.

(v) For each fiscal year following the filing of the notice described in paragraph (f)(2)(i) of this section, the commodity pool operator may claim the extension of time by filing a statement containing the representations specified in paragraph (f)(2)(iv) of this section, at the same time as the pool's annual report.

(vi) Any notice or statement filed pursuant to paragraph (f)(2) of this section must be signed by the commodity pool operator in accordance with paragraph (h) of this section.

* * * * *

Issued in Washington, D.C. on October 31, 2000 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 00–28367 Filed 11–6–00; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 00N–1545]

Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations describing postmarketing reporting requirements to implement certain provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The proposed changes apply to drug products that are life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition and that were not originally derived from human tissue and replaced by a recombinant product. The proposed rule would implement provisions of the Modernization Act by requiring an applicant who is the sole manufacturer of one of these products to notify FDA at least 6 months before discontinuing manufacture of the drug product.

DATES: Submit written comments by February 5, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance for industry referred to in this proposed rule. Submit written requests for single copies of the guidance referred to in this proposal to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 1–888–CBERFAX or 301–827–3844. Send two self-addressed adhesive labels to assist the office in processing your request. Requests should be identified with the

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Introduction

On November 21, 1997, President Clinton signed into law the Modernization Act (Public Law 105–115). Section 131 of the Modernization Act amends the Federal Food, Drug, and Cosmetic Act (the act) by codifying new section 506C (21 U.S.C. 356c). Section 506C of the act requires manufacturers who are the sole manufacturers of certain drug products to notify us (FDA) at least 6 months before discontinuing manufacture of the products. We may reduce the 6-month notification period if good cause exists for the reduction. Under section 506C of the act, we must provide information to the public about the product discontinuance. The proposed revisions to our postmarketing reporting requirements described in this notice are intended to implement these new provisions of the act.

A presidential memoradum on plain language (June 1, 1998) directs each agency to write regulations that are simple and easy to understand. As a result, we prepared this proposed regulation consistent with our plain language initiative. Please send any comments you have on the clarity of the regulations to the Dockets Management Branch (address above).

II. Section 506C of the Act

Section 506C(a) of the act requires sole manufacturers of a drug product that meets the following three criteria to notify us at least 6 months before discontinuing manufacture of the product:

1. The product must be life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;
2. The product must have been approved under section 505(b) or (j) of the act (21 U.S.C. 355(b) or (j)); and
3. The product must not have been originally derived from human tissue and replaced by a recombinant product.

Under section 506C(b) of the act, we may reduce the 6-month notification period required under section 506C(a) if the manufacturer who seeks our reduction of the notification period certifies to us that good cause exists for the reduction. Section 506C(b) of the act provides examples of situations where good cause exists as follows:

- A public health problem may result from continuation of manufacturing for the 6-month period;
- A biomaterials shortage prevents the continuation of manufacturing for the 6-month period;
- A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;
- Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;
- The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (11 U.S.C. 701 *et seq.* and 1101 *et seq.*); or
- The manufacturer can stop making the product but still distribute it to satisfy existing market need for 6 months.

Section 506C(c) of the act requires us to distribute, to the maximum extent practicable, information to the public about the discontinuation of products described in section 506C(a).

III. Description of the Proposed Rule

A. Notification Requirements

Section 314.81(b)(3)(iii) (21 CFR 314.81(b)(3)(iii)) of our current regulations requires all applicants to notify us when they withdraw a drug product from sale in the United States. This notification must take place within 15 days of the withdrawal.

As described above, under section 506C(a) of the act, the sole manufacturer of a drug product that meets the following three criteria must notify us at least 6 months before discontinuing manufacture of the product:

1. The product must be life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;
2. The product must have been approved under section 505(b) or (j) of the act; and
3. The product must not have been originally derived from human tissue and replaced by a recombinant product.

We are proposing to amend our postmarketing reporting regulations in § 314.81 to implement these new statutory requirements. Proposed § 314.81(b)(3)(iii) would state that applicants who are sole manufacturers of these drug products must notify us at least 6 months before discontinuing manufacture of the products.

Under this proposal, a life supporting or life sustaining drug would be a drug product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. This definition of a life sustaining or life supporting product has been adapted from our regulations governing medical devices (21 CFR 860.3(e)). The Center for Devices and Radiological Health, in adopting the medical device interpretation of life sustaining or life supporting product (43 FR 32988, July 28, 1978), noted its reliance on the legislative history of the 1976 Medical Device Amendments to the act (Public Law 94–295) regarding the definition and application of the term (H. Rept. 94–1090, Medical Device Amendments, May 6, 1976 (Committee of Conference), p. 56).

We interpret the phrase ''debilitating disease or condition,'' as stated in section 506C(a) of the act, to mean serious disease or condition. The use of the phrase ''serious disease or condition'' is consistent with other regulations (e.g., Accelerated Approval of New Drugs and Biological Products for Serious or Life-Threatening Illnesses (21 CFR parts 314 subpart H and 601 subpart E) (accelerated approval rule)) and policy statements (e.g., guidance for industry, ''Fast Track Drug Development Programs—Designation, Development, and Application Review'' (October 1998) (fast track guidance)). As discussed in the preamble to the proposed accelerated approval rule (57 FR 13234, April 15, 1992), determination of the seriousness of a condition is a matter of judgment, but generally is based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. The fast track guidance elaborates on our current approach to determining whether a disease or condition is serious by providing several examples of situations in which a drug would be considered to prevent a serious disease or condition. The fast track guidance is available at the CDER and CBER addresses above.

By the terms of the statute, the requirements of section 506C of the act are limited to products that we have approved under the authority of section 505(b) or (j) of the act. To implement this limitation, products we have approved under the authority of section 351 of the Public Health Service Act (42 U.S.C. 262) would not be covered by this proposed regulation.

To implement the last requirement of section 506C(a) of the act, the proposed rule specifically excludes from the notification requirements a manufacturer whose product was originally derived from human tissue and was subsequently replaced by a recombinant product.

B. Reduction in the Discontinuance Notification Period

Under section 506C(b) of the act, we may reduce the 6-month notification period if we find good cause for the reduction, generally as established by manufacturer certification that good cause exists for the reduction.

FDA is proposing § 314.91 to implement section 506C(b) of the act. Proposed § 314.91 would allow the agency to reduce for good cause the 6-month notification period required under proposed § 314.81(b)(3)(iii)(*a*). Under proposed § 314.91(b), we can reduce the 6-month discontinuance notification period when we find good cause exists for the reduction. We may find good cause exists based on information certified by an applicant in a written request for a reduction of the discontinuance notification period. In limited circumstances, we also may find good cause exists based on information already known to us. These circumstances can include the withdrawal of the drug from the market based upon formal regulatory action (e.g., under the procedures described 21 CFR 314.150) for the publication of a notice of opportunity for a hearing describing the basis for the proposed withdrawal of a drug from the market) or resulting from consultations between the applicant and us. To assist a manufacturer in requesting a reduction in the notification period, proposed § 314.91(c)(1) provides a template for certification that good cause exists.

Proposed § 314.91 repeats the examples in section 506C of the act and describes the information an applicant must provide FDA to establish good cause:

- To certify that a public health problem may result from continuation of manufacturing for the 6-month period, a manufacturer would need to describe in detail the potential threat to the public health (proposed § 314.91(d)(1)).
- To certify that a biomaterials shortage prevents the continuation of manufacturing for the 6-month period, the manufacturer would need to: (1) Describe in detail the steps it has taken to try to secure an adequate supply of biomaterials to enable manufacturing during the 6-month period, and (2) explain why the biomaterials could not be secured (proposed § 314.91(d)(2)).
- To certify that a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period, the manufacturer would need to explain to the agency in detail the potential liability problem (proposed § 314.91(d)(3)).
- To certify that continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer, the manufacturer would need to describe in detail the financial impact on the company of manufacturing the drug product for 6 more months (proposed § 314.91(d)(4)).
- To certify that the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code, the manufacturer would need to send the agency documentation of the filing or proof that the filing occurred (proposed § 314.91(d)(5)).
- To certify that the manufacturer can stop making the product but still distribute it to satisfy existing market need for 6 months, the manufacturer would need to describe in detail its processes: (1) To determine market need and (2) to ensure distribution for the 6-month period (proposed § 314.91(d)(6)).

A manufacturer may also establish good cause by other circumstances (proposed § 314.91(d)(7)). To certify that other circumstances establish good cause, the manufacturer would need to fully explain to us the need for a reduction in the 6-month notification period.

In assessing a manufacturer's assertion that good cause exists to warrant a reduction in the notification period, we may consider information in the certification and other information already available to us.

C. Disclosure of Discontinuance Information to the Public

As noted above, section 506C(c) of the act states that to the maximum extent practicable, we are to distribute information to the public about the discontinuation of products described in section 506C(a).

To implement section 506C(c) of the act, we are proposing § 314.81(b)(3)(iii)(*d*). Under this regulation, we would publicly disclose a list of the drugs that will be discontinued under the rule. The listing of discontinued products would include:

- The brand and generic name, the manufacturer, and indication(s) of the drug product;
- Whether a reduction in the notification period was granted by the agency under proposed § 314.91;
- If applicable, the reason(s) for a notification period of less than 6 months; and
- Any additional information the agency may have regarding anticipated product availability.

The proposed rule would require this information to be distributed through posting on the Internet and notice in the **Federal Register** (proposed § 314.81(b)(3)(iii)(*c*)).

IV. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires agencies to prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

We believe that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in these two statutes. As shown below, the proposed rule will result in minimal additional costs to industry. As a result, the proposed rule is not significant as defined by the Executive Order. We have further determined, as described below, that the proposed rule would affect only about one manufacturing firm per year. Therefore, the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities and will not require further analysis under the Regulatory Flexibility Act. The Unfunded Mandates Reform Act does not require us to prepare a statement of costs and benefits for the proposed rule because the proposed rule in any 1-year expenditure would not exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

The proposed rule would require that manufacturers of certain drug products notify the agency at least 6 months before discontinuing their manufacture. As explained in section V of this

document, the regulatory conditions that trigger this requirement occur only infrequently. Based on agency experience, we estimate that such circumstances would occur no more than once per year. Moreover, the proposed notification requirement would impose a significant burden only when market conditions deteriorate so quickly that firms could not foresee the desired action 6 months in advance. Most pharmaceutical firms rely on established long-term marketing plans.

For those very few instances where a manufacturer needs to discontinue production and could not provide 6-months notice, the proposed rule permits us to reduce the notification period for good cause. Manufacturers can request a reduced notification period by submitting a written certification, based on considerations such as public health, legal liability, biomaterial shortage, or substantial economic hardship. A certification of substantial economic hardship would need to demonstrate that the reduced notification period was necessary to avoid substantial economic hardship to the manufacturer.

V. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, we invite comment on: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements

Description: The proposed rule would implement section 506C of the act and would require applicants who are the sole manufacturers of certain drug or biologic products to notify us at least 6 months before discontinuing the manufacture of the product. For the rule to apply, a product would need to meet the following three criteria:

1. The product must be life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;
2. The product must have been approved by FDA under section 505(b) or (j) of the act; and
3. The product must not have been originally derived from human tissue and replaced by a recombinant product.

The proposed rule would allow us to reduce the 6-month notification period if we find good cause for the reduction. An applicant would be able to request that we reduce the notification period by certifying that good cause for the reduction exists. Under the proposed rule, we would also publicly disclose information about the drugs that are discontinued under the rule. Existing regulations, which appear in 21 CFR part 314, establish postmarketing reporting requirements for approved drugs. Current § 314.81(b)(3)(iii) (OMB Control No. 0910–0001), which would be renumbered § 314.81(b)(3)(iv) under the proposed rule, requires an applicant to notify us within 15 days of withdrawing a drug product from sale. This proposed rule would add two new reporting requirements.

A. Notification of Discontinuance

Under the proposed rule, at least 6 months before an applicant intends to discontinue manufacture of a product, the applicant would need to send us written notification of the discontinuance. For drugs regulated by CDER, the applicant would send notification to the director of the division in CDER that is responsible for the application, with one copy to the CDER Drug Shortage Coordinator and one copy to CDER's Drug Listing Branch. For drugs regulated by CBER, the applicant would send notification to the Director of CBER. We would require that the notification be sent to these offices to ensure that our efforts regarding the discontinuation of the product are commenced in a timely manner. We intend to work with members of the industry and with the applicant during the 6-month notification period to ease patient transition from the drug that will be discontinued to alternate therapy.

B. Certification of Good Cause

We may reduce the 6-month notification period if we find good cause for the reduction. As described in section 506C(b) of the act and proposed § 314.91, an applicant would be able to establish good cause by submitting written certification to the director of the division in CDER that is responsible for the application, with one copy to the CDER Drug Shortage Coordinator and one copy to CDER's Drug Listing Branch or, for drugs regulated by CBER, to the Director of CBER, that:

- A public health problem may result from continuation of manufacturing for the 6-month period (proposed § 314.91(d)(1));
- A biomaterials shortage prevents the continuation of manufacturing for the 6-month period (proposed § 314.91(d)(2));
- A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period (proposed § 314.91(d)(3));
- Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer (proposed § 314.91(d)(4));
- The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (proposed § 314.91(d)(5));
- The manufacturer can stop making the product but still distribute it to satisfy existing market need for 6 months (proposed § 314.91(d)(6)); or
- Other good cause exists for a reduction in the notification period (proposed § 314.91(d)(6)).

With each certification described above, the applicant would need to describe in detail the basis for the applicant's conclusion that such circumstances exist. We would require that the written certification that good cause exists be submitted to the offices identified above to ensure that our efforts regarding the discontinuation take place in a timely manner.

Description of Respondents: An applicant who is the sole manufacturer and who intends to discontinue marketing of a drug product that: (1) Is life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition; (2) was approved by FDA under section 505(b) or (j) of the act; and (3) was not originally derived from human tissue and replaced by recombinant product.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for notification of product discontinuance and certification of good cause under this proposed rule.

Notification of Discontinuance: Based on data collected from the CDER drug

shortage coordinator, CDER review divisions, and CBER review offices in fiscal year (FY) 1999, one applicant discontinued manufacture of one product meeting the criteria of section 506C of the act. Each applicant meeting the criteria would be required under proposed § 314.81(b)(3)(iii) to notify the agency of the discontinuance at least 6 months before manufacturing ceased. Although the procedures for notifying the agency that are set forth in the proposed rule were not in place in FY 1999, we estimate that the number of manufacturers who would be required to notify us of discontinuance would remain the same. Therefore, the number of respondents is estimated to be one. The total annual responses are the total number of notifications of discontinuance that are expected to be submitted to CDER or CBER in a year. In FY 1999, an applicant would have been required to notify us of one product discontinuance under the proposed procedures. We estimate that the total annual responses will remain the same, averaging one response per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a notification of product discontinuance, including the time it takes to gather and copy the statement. Based on experience in working with applicants regarding similar collections of information, we estimate that approximately 2 hours on average would be needed per response. Therefore, we estimate that 2 hours will be spent per year by respondents notifying us of a product discontinuance under these proposed regulations.

Certification of Good Cause: Based on data collected from the CDER drug shortage coordinator, CDER review divisions, and CBER review offices in FY 1999, one applicant discontinued manufacture of one product meeting the criteria of section 506C of the act. Each applicant would have the opportunity under proposed § 314.91 to request a reduction in the 6-month notification period by certifying to us that good cause exists for the reduction. We do not expect that each eligible applicant will certify that good cause exists for a reduction. Furthermore, the number of applicants who would be in a position to request a reduction is quite small. Therefore, the number of respondents is estimated to be one. The total annual responses are the total number of notifications of discontinuance that are expected to be submitted to us in a year. We estimate that the total annual responses will remain small, averaging one response per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the detailed information certifying that good cause exists for a reduction in the notification period, including the time it takes to gather and copy the documents. Based on experience in working with applicants regarding similar collections of information, we estimate that approximately 16 hours on average would be needed per response. Therefore, we estimate that 16 hours will be spent per year by respondents certifying that good cause exists for a reduction in the 6-month notification period under proposed § 314.91.

We invite comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification of discontinuance (proposed § 314.81(b)(3)(iii))	1	1	1	2	2
Certification of good cause (proposed § 314.91)	1	1	1	16	16
Total					18

[1]There are no capital costs or operating and maintenance costs associated with this collection.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments on this information collection by December 7, 2000, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the order, and, consequently, a federalism summary impact statement is not required.

VII. Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by February 5, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. Electronic Access

Copies of the guidance for industry referred to in this proposed rule are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 314 be amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

1. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

2. Section 314.81 is amended by redesignating paragraph (b)(3)(iii) as (b)(3)(iv); by removing from newly redesignated paragraph (b)(3)(iv)(*c*) the phrase ''(b)(3)(iii)'' and adding in its place the phrase ''(b)(3)(iv)''; and by adding new paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Notification of discontinuance.* (*a*) An applicant who is the sole manufacturer of an approved drug product must notify FDA in writing at least 6 months prior to discontinuing manufacture of the drug product if:

(*1*) The drug product is life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition; and

(*2*) The drug product was not originally derived from human tissue and replaced by a recombinant product.

(*b*) For drugs regulated by the Center for Drug Evaluation and Research (CDER), the notification required by paragraph (b)(3)(iii)(*a*) of this section must be sent to the director of the division responsible for the application as identified to the applicant under § 314.440(a)(1). The applicant must send one copy of the notification to the Drug Shortage Coordinator, at the address of the Director of CDER, and one copy of the notification to the Drug Listing Branch. For drugs regulated by the Center for Biologics Evaluation and Research (CBER), the notification required by paragraph (b)(3)(iii)(*a*) of this section must be sent to the Director of CBER.

(*c*) FDA will publicly disclose a list of all drug products to be discontinued under paragraph (b)(3)(iii)(*a*) of this section. If the notification period is reduced under § 314.91, the list will state the reason(s) for such reduction and the anticipated date that manufacturing will cease.

* * * * *

3. Section 314.91 is added to read as follows:

§ 314.91 Obtaining a reduction in the discontinuance notification period.

(a) *What is the discontinuance notification period?* The discontinuance notification period is the 6-month period required under § 314.81(b)(3)(iii)(*a*). The discontinuance notification period begins when an applicant who is the sole manufacturer of certain products notifies FDA that it will discontinue manufacturing the product. The discontinuance notification period ends when manufacturing ceases.

(b) *When can FDA reduce the discontinuance notification period?* FDA can reduce the 6-month discontinuance notification period when it finds good cause exists for the reduction. FDA may find good cause exists based on information certified by an applicant in a request for a reduction of the discontinuance notification period. In limited circumstances, FDA may find good cause exists based on information already known to the agency. These circumstances can include the withdrawal of the drug from the market based upon formal FDA regulatory action (e.g., under the procedures described in § 314.150 for the publication of a notice of opportunity for a hearing describing the basis for the proposed withdrawal of a drug from the market) or resulting from the applicant's consultations with the agency.

(c) *How can an applicant request a reduction in the discontinuance notification period?* (1) The applicant must certify in a written request that, in its opinion and to the best of its knowledge, good cause exists for the reduction. The applicant must submit the following certification:

The undersigned certifies that good cause exists for a reduction in the 6-month notification period required in § 314.81(b)(3)(iii)(*a*) for discontinuing the manufacture of (*name of the drug product*). The following circumstances establish good cause (*one or more of the circumstances in paragraph (d) of this section*).

(2) The certification must be signed by the applicant or the applicant's attorney, agent (representative), or other authorized official. If the person signing the certification does not reside or have a place of business within the United States, the certification must contain the name and address of, and must also be signed by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(3) For drugs regulated by the Center for Drug Evaluation and Research (CDER), the certification must be submitted to the director of the division that is responsible for the application as identified to the applicant under § 314.440(a)(1). One copy of the certification must be sent to the Drug Shortage Coordinator, at the address of the Director of CDER, and one copy of the certification must be sent to the Drug Listing Branch. For drugs regulated by the Center for Biologics Evaluation and Research (CBER), the certification must be submitted to the Director of CBER.

(d) *What circumstances and information can establish good cause for a reduction in the discontinuance notification period?* (1) A public health problem may result from continuation of manufacturing for the 6-month period. This certification must include a detailed description of the potential threat to the public health.

(2) A biomaterials shortage prevents the continuation of the manufacturing for the 6-month period. This certification must include a detailed description of the steps taken by the applicant in an attempt to secure an adequate supply of biomaterials to enable manufacturing to continue for the 6-month period and an explanation of why the biomaterials could not be secured.

(3) A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period. This certification must include a detailed description of the potential liability problem.

(4) Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer. This certification must include a detailed description of the financial impact of continuing to manufacture the drug product over the 6-month period.

(5) The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (11 U.S.C. 701 *et seq.* and 1101 *et seq.*). This certification must be accompanied by documentation of the filing or proof that the filing occurred.

(6) The manufacturer can continue distribution of the drug product to satisfy existing market need for 6 months. This certification must include a detailed description of the manufacturer's processes to ensure such distribution for the 6-month period.

(7) Other good cause exists for the reduction. This certification must include a detailed description of the need for a reduction.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28519 Filed 11–6–00; 8:45 am]

BILLING CODE 4160–01–F