Volatile flammable liquid. A flammable liquid having a flash point below 38 degrees C (100 degrees F) or whose temperature is above its flash point, or a Class II combustible liquid having a vapor pressure not exceeding 40 psia (276 kPa) at 38° C (100° F) whose temperature is above its flash point.

Voltage. (Of a circuit.) The greatest root-mean-square (effective) difference of potential between any two conductors of the circuit concerned.

Voltage, nominal. A nominal value assigned to a circuit or system for the purpose of conveniently designating its voltage class (as 120/240, 480Y/277, 600, etc.). The actual voltage at which a circuit operates can vary from the nominal within a range that permits satisfactory operation of equipment.

Voltage to ground. For grounded circuits, the voltage between the given conductor and that point or conductor of the circuit that is grounded; for ungrounded circuits, the greatest voltage between the given conductor and any other conductor of the circuit.

Watertight. So constructed that moisture will not enter the enclosure.

Weatherproof. So constructed or protected that exposure to the weather will not interfere with successful operation. Rainproof, raintight, or watertight equipment can fulfill the requirements for weatherproof where varying weather conditions other than wetness, such as snow, ice, dust, or temperature extremes, are not a factor.

Wet location. See *"Location."*

[FR Doc. 86-15400 Filed 7-10-86; 8:45 am]
BILLING CODE 4510-26-M

federal register

Friday
July 11, 1986

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 60

Patent Term Restoration Regulations; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 60

[Docket No. 85N-0300]

Proposed Patent Term Restoration Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to implement the patent term restoration provisions (Title II) of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417). Patent term restoration, extending patent life, is available for certain patents related to human drug products, as defined in 35 U.S.C. 156(f)(2), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

DATES: Comments by October 9, 1986. FDA proposes that any final rule based on this proposal become effective 60 days after its publication in the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the act). Title II of the act amended the U.S. patent laws to provide patent term restoration for certain patents related to human drugs (including antibiotics and biologics) as defined in 35 U.S.C. 156(f)(2), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). In the **Federal Register** of June 28, 1985 (50 FR 26791), FDA published an advance notice of proposed rulemaking, soliciting comments on the agency's implementation of Title II. This proposal includes a discussion of the five comments that FDA received in response to that notice.

Administration of Title II is divided between FDA and the U.S. Patent and Trademark Office (PTO). PTO has issued guidelines (and will soon promulgate regulations) governing the format, content, and submission of patent term restoration applications. 1047 *Official Gazette Patent Office* 16 (October 9, 1984). PTO is responsible for accepting applications, determining whether a patent is eligible for patent extension, and, if appropriate, issuing a patent extension. FDA assists PTO in its eligibility determination, and is responsible for determining the length of the FDA review period for the product related to the patent. If petitioned to do so, FDA also will determine whether the applicant acted with due diligence and hold an informal hearing on a due diligence determination.

Title I of the act amended the Federal Food, Drug, and Cosmetic Act to greatly expand the number of drugs for which FDA may accept abbreviated new drug applications (ANDA's). It also provides partial marketing protection ("exclusivity") for certain human drugs requiring full new drug applications (NDA's). The ANDA provisions require FDA to address, for the first time, certain patent-related issues before allowing generic drug manufacturers to market patented drug products. Regulations implementing the provisions of Title I of the act will be the subject of a separate rulemaking proceeding.

The proposed regulations set forth in this document, if adopted as final regulations, will implement FDA's responsibilities under Title II.

II. Background

Patents grant patent holders the right to exclude others from making, using, or selling an invention. The granting of this exclusive right is designed to encourage innovation. The patent holder will reap greater profits if protected from direct competition. These profits are intended to serve as incentives for creating innovative products that benefit the public.

The patent term in the United States is 17 years. However, the effective patent term is frequently less than 17 years because patents are often obtained before products are actually marketed. Many factors influence the length of the effective patent term, including Federal regulation. The Federal Food, Drug, and Comestic Act and the Public Health Service Act require that certain products receive FDA approval before marketing. For example, new human drug products generally must undergo extensive testing in animals and humans to show that the drugs are both safe and effective before FDA will approve the product for marketing.

The prospect of short effective patent terms, coupled with rising research and development costs, led the pharmaceutical industry and others to assert that short effective patent terms "would result in decreased expenditures for reseach and development and, eventually, a decline in the introduction of new drugs." H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 17 (1984). Consequently, in order to stimulate product development and innovation, Congress began considering ways to extend patent life to compensate patent holders for marketing time lost while awaiting government approval. The concept of patent term restoration was the result.

III. The Drug Price Competition and Patent Term Restoration Act of 1984

Since the late 1970's, Congress has considered legislation to address the problem of short effective patent terms. During the 96th Congress, the House of Representatives considered patent term restoration legislation, and in the 97th Congress, the Senate unanimously passed, and the House of Representatives narrowly failed to approve, a patent term restoration bill.

Comprehensive legislative proposals were not the only congressional actions on patent term restoration. For example, in 1983, Congress added sections 155 and 155A to the patent statute (Title 35 of the United States Code). These sections granted patent term restoration to specific products (e.g., section 155 pertains to aspartame). Congress has also passed private bills to extend patents for certain products.

In the 98th Congress, a bill was introduced that included both patent term restoration and ANDA provisions. The compromise bill, which eventually became the Drug Price Competition and Patent Term Restoration Act of 1984, was passed in the Senate on August 10, 1984, and then unanimously approved in the House on September 6, 1984. The President signed this bill into law on September 24, 1984.

Title II of the act contains the patent term restoration provisions under which patent holders can potentially receive an extension equal to approximately half the time required to test the product before submitting the marketing application, plus all the time require for FDA to approve the marketing application.

Title II places several limits, however, on the actual length of patent extension. The period of extension may not exceed 5 years. The period of patent extension plus the patent term remaining after approval of the product may not exceed 14 years. If a marketing applicant did not act with due diligence during a portion of the product's regulatory review period, that time may not be counted toward patent extension.

In the **Federal Register** of March 8, 1985 (50 FR 9424), the Commissioner of Food and Drugs redelegated to the Associate Commissioner for Health Affairs the performance of the functions required of the Secretary of Health and Human Services under 35 U.S.C. 156. See 21 CFR 5.27. This delegation, however, does not include the holding of informal hearings under 33 U.S.C. 156(d)(2)(B)(ii).

IV. Provisions of this Proposal

The agency is proposing to codify these regulations in new 21 CFR Part 60.

Subpart A of the proposed regulations contains general provisions, including definitions. Proposed Subpart B contains provisions relating to FDA's assistance to PTO in determining eligibility. In Subpart C, the agency is proposing regulations to govern the determination of regulatory review periods. Subpart D contains provisions for challenging a regulatory review period determination on the grounds that an applicant did not diligently pursue premarketing approval. Standards for determining due diligence are also proposed. In Subpart E, the agency is proposing regulations governing informal hearings on the issue of due diligence.

A. General Provisions

In Subpart A, the agency is proposing definitions for purposes of Title II that are consistent, wherever possible, with definitions used in other areas of food and drug law.

Proposed § 60.3(a) incorporates the definitions contained in Title II for "approved product," "due diligence," "product," "human drug product," "major health or environmental effects test," "informal hearing," "patent," and "regulatory review period." For the sake of completeness, proposed definitions in § 60.3(b) incorporate the definitions of "product" and "human drug product" along with the related terms defined in that paragraph. The incorporated definitions of "major health or environmental effects test," "due diligence," "informal hearing," and "regulatory review period" appear in other sections of the proposed regulations.

Proposed § 60.3(b) contains additional specific definitions for the terms "active ingredient," "medical device," "food additive," and "color additive." Although the term "active ingredient" appears in Title II's definition of human drug product, FDA has previously established a definition for this term. FDA regulations define "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals" including those components that may undergo chemical change in the drug product's manufacture and be present in the drug product in a modified form intended to furnish the specified activity or effect. See 21 CFR 210.3(b)(7). Accordingly, this proposal adopts the established definition of active ingredient. Additionally, the definitions of "medical device," "food additive" and "color additive" in proposed § 60.3(b) refer to specific provisions of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to make clear that only products subject to a regulatory review period, as defined in Title II, are included in the definition.

Definitions of "applicant," "application," "marketing applicant," and "marketing application" are included in proposed § 60.3(b) to emphasize the distinction between applicants or applications for patent term extension and applicants or applications for marketing approval.

B. Eligibility Assistance

FDA is proposing in new § 60.10 to implement the agency's role in assisting PTO in determining eligibility for patent term restoration under 35 U.S.C. 156 (a) and (d)(1). Under those sections of the U.S. Code, a patent term restoration applicant must satisfy six conditions. First, the applicant must show that the patent has not expired (35 U.S.C. 156(a)(1)). Second, the applicant must establish that the patent has not been previously extended (35 U.S.C. 156(a)(2)). Third, the patent owner or its agent must submit the application, including details regarding the patent and the activities undertaken to secure FDA approval (35 U.S.C. 156(a)(3)). Fourth, the applicant must establish that the product was subject to a regulatory review period before its commercial marketing or use (35 U.S.C. 156(a)(4)). Fifth, the applicant must show that the product either represents the first permitted commercial marketing or use of the product after such regulatory review period or, in the case of a product manufactured under a process patent that primarily uses recombinant deoxyribonucleic acid (DNA) technology, represents the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent (35 U.S.C. 156(a)(5)). Finally, the applicant must submit the application for patent term restoration to PTO within 60 days of FDA approval of the commercial marketing application (35 U.S.C. 156(d)(1)).

Although the Commissioner of Patents and Trademarks is to decide whether an applicant has satisfied these six conditions, FDA possesses expertise and records essential to deciding whether the last four requirements have been satisfied. Consequently, to facilitate eligibility decisions, FDA, in cooperation with PTO, has developed the procedures proposed in § 60.10. These procedures will be explained in greater detail in a separate memorandum of understanding between PTO and FDA (currently in process).

The agency proposes that, upon written request from PTO, FDA will advise PTO whether the product underwent a regulatory review period within the meaning of 35 U.S.C. 156(g) before commercialization and whether such marketing approval represents the first commercial marketing or use of that product. In order to implement 35 U.S.C. 156(a)(5)(B), which provides for the special case of a process patent using recombinant DNA technology (techniques that involve recombination of heterologous nucleic acids, e.g., in vitro DNA or RNA gene splicing, cell fusion hybridoma technology), the agency proposes that in such cases FDA will state whether the approved commercial marketing of the product is the first use of the product manufactured under the process claimed in the patent. FDA also proposes to inform PTO whether the patent term restoration application was received within 60 days after the product was approved. Additionally, § 60.10 of the proposed rule explains that FDA may provide PTO with any other information relevant to PTO's determination whether the patent is eligible for extension. Finally, § 60.10(b) of the proposed rule would make such

correspondence available to the applicant and to the public.

C. Regulatory Review Period Determinations

1. FDA action or regulatory review period determinations.

Proposed § 60.20 would implement procedures currently employed by the agency for regulatory review period determinations.

Under the proposal, FDA will consult its records and experts to verify the dates contained in an application, where possible, and to determine a product's regulatory review period under proposed § 60.22. Once the regulatory review period has been determined, FDA will notify both PTO and the applicant of the determination, file a copy of the determination in a docket for the application located in FDA's Dockets Management Branch, and publish the determination in the **Federal Register**. The **Federal Register** notice will state the applicant's name, the product's trade name (and generic name, if the product is a drug), the product's approved uses and patent number, an explanation of any discrepancies between the dates in the application and FDA records, and the regulatory review determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

One comment submitted in response to the June 28, 1985, notice suggested that FDA include an eligibility section in a regulatory review period determination that would identify a drug product's active ingredient and list any previously approved drugs containing the same active ingredient.

The agency does not publish a regulatory review period determination if the human drug in question is not the first commercial use of the active ingredient. A reference to a drug's active ingredient is currently included in **Federal Register** notices of regulatory review period determination, and FDA considers this sufficient to inform interested parties about the drug product under consideration.

A second comment suggested that FDA insert a definition of "initially submitted" in the supplementary information section of its **Federal Register** notices and state the specific date on which a marketing application or petition was "initially submitted."

FDA does not believe it necessary to define the term "initially submitted" in every **Federal Register** notice. Proposed § 60.22(d) defines the term "initially submitted" consistent both with current agency practice and with the legislative history of the act. See H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 44 (1984). FDA agrees that the specific date on which an application or petition is initially submitted should be referred to in its **Federal Register** notices setting forth a regulatory review period determination. Consequently, FDA includes in its **Federal Register** notices the dates used to determine a product's regulatory review peiod, including the date upon which the marketing application was "initially submitted."

2. Testing and Approval Phases of the Regulatory Review Period.

Proposed § 60.22 defines the testing and approval phases of a regulatory review period for human drugs, food and color additives, and medical devices in accordance with 35 U.S.C. 156(f)(3) and (g) (1), (2), and (3). Additionally, the proposal considers the "clinical investigation" portion of the testing phase for medical devices to begin when an investigational device exemption (IDE) is finally approved, or, if the marketing applicant has given conditional IDE approval pending institutional review board (IRB) approval, when IRB approval has been obtained. If an IDE is not required, the proposal considers a clinical investigation to begin when IRB approval has been obtained, or, if neither IDE or IRB approval is required, on the date on which the device is first used with human subjects as part of a clinical investigation to secure FDA market approval.

The proposal also defines the terms "major health or environmental effects test" for purposes of calculating the testing phase for food and color additives, and "initially submitted" and "approved" for purposes of calculating the end of the testing phase and beginning of the approval phase for all applications subject to Title II.

Two comments submitted in response to the June 28, 1985, notice concerned the measurement of the 6-month requirement for a major health or environmental effects test. One comment cited several regulations that it suggested could trigger the beginning of a major health or environmental effects test whether or not the test article is exposed to the test system. Another comment focused on the type of action that would initiate a major health or environmental effects test and recommended that "a test should be considered as initiated the day that compliance with the good laboratory practice regulations (GLP's) begins* * *."

The agency has not adopted these suggestions in this proposal. The proposed definition is consistent with the statutory language and the legislative history. See 35 U.S.C. 156(f)(3); H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 43 (1984). Consequently, under the proposed rule, a major health or environmental effects test would be any test that is reasonably related to the evaluation of the product's health or environmental effects, produces data necessary for marketing approval, and is conducted over a 6-month period, excluding time spent analyzing or evaluating data.

In this proposal, FDA declines to treat any specific event as the start of the required 6-month period for a major health or environmental effects test. This decision is supported by the statutory language and made necessary by the differences between health and environmental effects tests. For example, compliance with GLP regulations might be inappropriate as a triggering event for an environmental effects test because an environmental effects test might not be subject to the GLP regulations. Furthermore, compliance with GLP regulations may not always signal the start of a test for health effects. A laboratory conducting studies for several products, for example, might have satisfied GLP regulations far in advance of testing the product at issue in the application. In such a case, compliance with GLP regulations would be unrelated to testing the product. The statutory language also argues against using GLP compliance as the start of a major health or environmental effects test because "the data [from a major health or environmental effects test must be] submitted to receive permission for commercial marketing or use." 35 U.S.C. 156(f)(3). Compliance with GLP regulations does not, in itself, yield such data.

Two other comments addressed an issue that FDA raised in the June 28, 1985, notice. In that notice, FDA asked for comment on whether multiphase studies, with discrete phases lasting less than 6 months but totalling more than 6 months, could constitute a major health or environmental effects test. One comment argued that human safety studies, animal studies, toxicity studies, and other tests required for premarket additive approval are interdependent (rather than independent) because the tests "have to be performed on a sequential basis for the results to be meaningful." Moreover, the comment declared, because most studies require several years of testing, FDA should not be overly concerned with short, multiphase studies. Another comment suggested that a "major health or environmental effects test" be construed

as a test or tests which by their overlapping nature "support or are intended to support applications for research or marketing permits for products regulated by the agency" whether or not each test individually takes 6 months or longer to perform.

Since the agency has not received a patent term restoration application for a food or color additive, the agency has elected to defer this issue until it has acquired sufficient information to make a decision. Hence, this proposed rule does not attempt to describe specifically which test might not constitute interdependent health or environmental effects tests, or whether the aggregate of interdependent, overlapping tests may meet the statutory 6-month period. Until FDA has acquired more experience in this area, each case will be reviewed on its own merits.

Under the proposed regulations, FDA will consider a marketing application "initially submitted" when the application or petition contains sufficient information to allow FDA to begin substantive review. For example, in the case of human drugs, an NDA that lacks the required manufacturing/controls section does not contain sufficient information to permit FDA review and would not be "initially submitted" under this proposal. On the other hand, if FDA has commenced substantive review of the NDA and simply requested additional miscellaneous information, the NDA would have been "initially submitted." The legislative history supports this interpretation of "initially submitted." See H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 44 (1984).

A marketing application is "approved" under proposed § 60.22(d) only on the date FDA notifies the applicant in writing that the application is approved. For example, for human drug products, an approval letter will be issued when the only conditions which must be met prior to marketing relate to minor editorial labeling deficiencies as described in § 314.105, and will signify approval of a marketing application; while an "approvable" letter issued under § 314.110 (which requires the applicant to take further substantive actions to meet certain conditions or supply additional information prior to marketing) will not signify approval.

3. Revision of Regulatory Review Period Determinations

The proposed regulations would establish a procedure under § 60.24 that allows any person to request a revision of a regulatory review period determination within 60 days after the publication of that determination in the **Federal Register.** The person requesting a revision must explain the basis of the requested revision and may submit evidence to support its position. FDA may provide the applicant an opportunity to respond to the request for revision. Any revision under this section will be made under proposed § 60.24, and FDA will notify both PTO and the applicant of any revision and publish that revision in the **Federal Register.**

FDA intends proposed § 60.24 to apply to those situations in which a person believes that there was an error in the dates used by or supplied to FDA to determine a product's regulatory review period. FDA has already applied this procedure for an applicant who discovered a discrepancy between its records and FDA's records. The applicant informed FDA of the discrepancy and submitted written evidence to support its position. FDA reviewed the evidence, found the applicant correct, and amended its determination.

4. Final Action on Regulatory Review Period Determinations

Proposed § 60.26 describes the circumstances in which FDA will consider a regulatory review period determination final. In general, a regulatory review period determination is final upon expiration of the 180-day period allowed for filing a due diligence petition. Once this period expires, FDA will notify PTO and the applicant that the determination is final and will file a copy of the notification in the docket established for the application in FDA's Dockets Management Branch. The determination is not final if, before the expiration of the 180-day period, PTO or FDA receives new information that affects the regulatory review period determination, such as evidence that one of the dates used in the regulatory review period determination is erroneous, or receives a request for a regulatory review period revision, a due diligence petition, or a request for a due diligence hearing under other sections of the proposed regulations. If one of these events intercedes, the regulatory review period determination is not final until the 180-day period expires or the request or petition is resolved, whichever is later.

5. Time Frame for Determining Regulatory Review Periods

Proposed § 60.28 would implement 35 U.S.C. 156(d)(2)(A), which sets time limits for FDA to determine a product's regulatory review period, notify PTO of the determination, and publish the determination in the **Federal Register.** Additionally, FDA proposes to notify the applicant of the regulatory review period determination.

The proposal also addresses two situations not covered by Title II. First, under proposed § 60.28(b), FDA may extend the 30-day limit for regulatory review period determinations whenever the determination process is suspended due to FDA action, PTO action, or the receipt of new information by either agency that warrants an extension. Second, proposed § 60.28(c) would provide that the time limit does not apply whenever an applicant withdraws the application or PTO declares the patent ineligible for patent term restoration. These provisions would help avoid situations in which the 30-day time limit would require FDA to publish a regulatory review period determination based on incorrect or incomplete information, or a moot application.

D. Due Diligence Petitions

The proposed regulations contained in Subpart D govern the format and procedures to be followed when due diligence petitions are submitted and describe the standard by which due diligence will be measured. Under this proposed subpart, FDA would reduce the regulatory review period by the amount of time the applicant or the marketing applicant unreasonably delayed the agency's review.

1. Filing, Format, and Content of Petitions

Proposed § 60.30 would implement 35 U.S.C. 156(d)(2)(B)(i), which allows any person to file a petition with FDA challenging a regulatory review period determination by alleging that the applicant did not act with "due diligence" in pursuing FDA approval of the product. Proposed § 60.30(a) states that any person may file a due diligence petition but that the petition must be filed no later than 180 days after the publication of the product's regulatory review period determination in the **Federal Register.** Proposed § 60.30(b) establishes the general format and filing procedures for due diligence petitions by adopting, with the minor variations discussed below, existing FDA procedures contained in 21 CFR 10.20 and 10.30 applicable to citizen petitions.

In proposed § 60.30 (c) and (d), FDA sets forth additional requirements for due diligence petitions which are not contained in 21 CFR 10.20 and 10.30. For example, under proposed § 60.20(c), the petitioner must claim that the applicant did not act with due diligence during some part of the regulatory review period. However, even though the act

places the burden of proof on the petitioner to make the necessary showing that the applicant failed to act with due diligence, the proposed regulation does not require extensive evidence of the applicant's lack of due diligence, partly because this type of evidence usually is not readily available to prospective petitioners. See H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 41 (1984). Instead, the proposed regulation adopts the standard enunciated in the legislative history by requiring "sufficent facts to merit an investigation by FDA of whether the applicant acted with due diligence." See *id.* at 42. Proposed § 60.34, discussed below, gives additional guidance regarding the petitioner's initial burden by stating the circumstances under which FDA may reject the petition without first conducting a due diligence investigation.

Proposed § 60.30(d) would require the petitioner to serve a copy of the petition on the applicant. The purpose of this requirement is to provide the applicant with an opportunity to respond to the petition within the short 90-day statutory time limit set for FDA action on the petition. See 35 U.S.C. 156(d)(2)(B)(i).

2. Applicant Response to Petition

Proposed § 60.32 provides the applicant with an opportunity to respond to the due diligence petition. Because FDA action on the petition could affect the length of patent term restoration granted to the applicant, the agency is proposing a mechanism by which the applicant may provide some input into the due diligence determination at an early stage.

The proposed rule requires the applicant to respond to the petition within 10 days of its receipt of a copy of the petition. Under the act, FDA must render a decision on the due diligence petition within 90 days of FDA's receipt of the petition. This short statutory period compels FDA to permit only 10 days for the applicant to file its response to the petition.

Proposed § 60.32(b) would limit the applicant's response to the issues raised in the due diligence petition. This provision is designed to exclude irrelevant or immaterial information in the applicant's response.

3. FDA Action on Petitions

Proposed § 60.34 contemplates two possible actions on a due diligence petition. FDA may deny the petition without conducting a due diligence investigation. Alternatively, FDA may investigate the applicant's due diligence and make a "due diligence determination" based on the investigation. The proposal also reflects the time limit contained at 35 U.S.C. 156(d)(2)(B)(i), which requires FDA action on a due diligence petition within 90 days after FDA receives the petition.

Under proposed § 60.34(b), FDA would be able to summarily deny a due diligence petition in four situations. These instances are where the petition: (1) Fails to conform to the filing requirements of 21 CFR 10.20; (2) fails to contain the information required by 21 CFR 10.30; (3) fails to provide sufficient facts or reasonable allegations that could be used to demonstrate a lack of due diligence; or (4) fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if true, the maximum patent extension sought in the application would not be affected. This last provision, proposed § 60.34(b)(4), would preclude the unnecessary expenditure of FDA resources in investigating due diligence petitions that are essentially moot because they cannot affect the potential patent extension.

Conversely, under proposed § 60.34(c), FDA may summarily grant a due diligence petition when there is no controversy over the petition. This provision, like § 60.34(b)(4), will help prevent useless due diligence investigations. If the applicant has no objection to a reduction in the regulatory review period, there is no reason to formally investigate the petition's allegations. Under proposed § 60.34(c), the agency would state in its due diligence determination that FDA granted the petition on the basis of the applicant's acquiescence.

4. Due Diligence Standard

The agency proposes that § 60.36(a) incorporate the definition of due diligence set forth in 35 U.S.C. 156(d)(3), which is that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. This flexible definition is consistent with congressional intent to apply a rule of reason or balancing approach to due diligence determinations.

In giving FDA the responsibility for determining due diligence, Congress recognized the agency's considerable expertise and experience in approving regulated products. Therefore, in determining whether an applicant pursued marketing approval with due diligence, FDA will examine the applicant's actions in light of the agency's experience with similar situations and products.

For example, FDA will consider whether an allegedly nondiligent applicant's delay in submitting clinical results to FDA was reasonable considering the usual amount of time applicants need to analyze test results. Similarly, if an allegedly nondiligent applicant relies on the incapacity of a principal investigator to explain a long delay in concluding a study, FDA will use its scientific expertise to determine whether the study was one that could be disrupted by the absence of the principal investigator, or whether the applicant could have easily found a substitute investigator without disrupting or delaying the study.

In developing this due diligence standard, FDA recognizes that the term "diligence" is used elsewhere in patent law and practice. For example, the provision of the patent law concerning certain circumstances under which a person is not entitled to a patent states that "[i]n determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the *reasonable diligence* of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." 35 U.S.C. 102(g) (emphasis added).

The courts have held, under the section above, that whether there has occurred a delay sufficient to constitute a lack of due diligence depends on the facts and circumstances of each case. *Correge* v. *Murphy*, 705 F.2d 1326 (Fed. Cir. 1983); *Shindelar* v. *Holdeman*, 628 F.2d 1337 (C.C.P.A. 1980). These decisions, while not controlling, can help illuminate the interpretation of "due diligence" under Title II. The proposed regulations reflect these decisions by establishing flexible rules, based on a case-by case approach, to determine whether an applicant acted with due diligence during the regulatory review period.

One comment submitted in response to the June 28, 1985, notice suggested that the agency determine due diligence by comparing the regulatory review period of the product to the so-called "ordinary" regulatory review period for similar products. Under the procedure proposed by the comment, if the applicant's regulatory review period was less than or equal to the time similar products ordinarily required, a conclusive presumption of due diligence would arise. However, if the regulatory review period exceeded the average, a rebuttable presumption of nondiligence would arise.

This proposal does not adopt the comment's suggestion because FDA believes that such a rule would be too inflexible. However, FDA does agree that comparisons of regulatory review periods may be relevant to a due diligence determination. Proposed § 60.36(a) explicitly refers to the regulatory review periods for comparable products as one of the factors that may be considered in FDA's due diligence determinations. Because the agency believes the length of regulatory review periods for comparable products is only one of several considerations which may be relevant to due diligence determinations, FDA has listed in proposed § 60.36(a) other factors that may affect due diligence determinations. FDA stresses that the eight factors listed in proposed § 60.36(a) merely illustrate the kinds of factors that FDA will consider in due diligence determinations.

The following examples indicate how FDA might apply this flexible approach to some of the eight factors. Under proposed § 60.36(a)(2), FDA may find a lack of due diligence where the regulatory review delay resulted from the applicant's failure to comply with FDA requirements. If, for example, FDA had informed the marketing applicant that it failed to conform to the current good manufacturing practice regulations, and the applicant took no steps toward compliance, the marketing applicant's inactivity could constitute a lack of due diligence. FDA's determination of a lack of due diligence might then result in a reduction of the regulatory review period equal to the amount of time the applicant took to conduct the inadequate study.

Proposed § 60.36(a)(3) would excuse delay solely attributable to FDA regulatory review action. This includes time spent by FDA scientists reviewing data submitted in support of a marketing application, and reasonable time attributable to FDA requests for additional information. The provision specifically would exclude delays caused by FDA enforcement or compliance action.

Under proposed § 60.36(a)4), non-FDA government action might excuse some delays. For example, if a State or local government enacted new laws, such as environmental protection statutes or worker safety ordinances, which interrupt the marketing applicant's testing phase, the delay caused by such governmental action might not constitute a lack of due diligence. Conversely, however, if the marketing applicant fails to comply with existing laws, the delay could constitute a lack of due diligence.

The unexpected unavailability of a principal investigator may, under proposed § 60.36(a)(5), be a valid excuse for some delay during the regulatory review period. Proposed § 60.36(a)(8), however, provides a check. For example, if the applicant could have replaced the investigator without interrupting the study itself, FDA could find that the delay demonstrated a lack of due diligence.

Proposed § 60.36(a) (6) and (8) together may permit an applicant to show that a delay resulted from the physical destruction of an essential testing facility and that the applicant acquired a new facility as soon as possible. This is consistent with the congressional direction that a temporary unavailability of test facilities would not constitute a lack of due diligence. See H. Rept. 857, 98th Cong., 2d Sess., Part 1, at 42 (1984).

The examples given above are intended only as illustrations of the types of factors that FDA may consider in its due diligence determinations. Principally, FDA will use its experience and expertise in premarketing approval to make the due diligence determination considering the facts and circumstances in each case.

Proposed § 60.36(b) would provide that, in making a due diligence determination, FDA may consider the actions of the patent term restoration applicant, the marketing applicant, and all those acting on behalf of them. This proposal recognizes that, due to business arrangements and other circumstances, the patent applicant frequently is not the same entity as the firm or person that pursues FDA approval of a marketing application.

E. Due Diligence Hearings

1. Request for Hearing

Proposed § 60.40 incorporates the statutory time-period requirement for filing a request for an informal hearing contained in 35 U.S.C. 156(d)(2)(B)(ii). Under this proposal, any person, including persons who filed a due diligence petition, the applicant, the marketing applicant, and third parties, may request a due diligence hearing. Because the agency proposes to adopt, with slight modifications, the hearing procedures at Part 16, the format for a hearing request is patterned on the format of the notice of opportunity for Part 16 hearings set forth at 21 CFR 16.22(a). The hearing request should be filed under the docket number of the **Federal Register** notice of the agency's regulatory review period determination and should specify the facts and the actions which are to be the subject of the hearing. The person requesting the hearing should be identified in the hearing request and certify that a true copy has been served upon interested parties, such as the patent term restoration applicant and the due diligence petitioner. This direct service on parties outside of FDA is necessary because of the requirement in Title II that FDA generally hold the hearing within 30 days of FDA's receipt of the request. Additionally, FDA must receive the hearing request within 60 days after the agency publishes its due diligence determination.

Proposed § 60.40(c) would require the person requesting a hearing to state whether it desires the hearing within 30 or 60 days after FDA's receipt of the request. This requirement implements the provision in Title II that a person requesting such a hearing may elect to have the hearing within 60 days. This requirement of an early decision by the party requesting the hearing will help FDA and the parties comply with the short statutory time frames applicable to due diligence hearings.

2. Notice of Hearing

Proposed § 60.42 would implement the hearing notice requirements contained in 35 U.S.C. 156(d)(2)(B)(ii). Title II request FDA to notify the patent holder and "any interested person" of the hearing and provide them with an opportunity to participate. The proposal would require that notice of the hearing be given to the applicant, the petitioner, and the person requesting the hearing (who might also be the applicant or the petitioner) 10 days before the hearing date.

3. Hearing Procedure

Proposed § 60.44 would establish the basic procedure, status of parties, standards, and burdens of proof to be used in due diligence hearings. Title II requires FDA, upon the request of any interested person, to hold an "informal hearing" on its due diligence determinations and defines an informal hearing as one having the meaning prescribed by section 201(y) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(y)). FDA's hearing regulations at 21 CFR Part 16 satisfy the requirements of section 201(y), and the agency proposes to adopt for its due diligence hearings the procedures contained in 21 CFR Part 16 with slight modifications.

Under the proposed rule, the basic procedures during and after the due diligence hearings would be governed

by Part 16 through a cross-reference in proposed § 60.44. Should any inconsistencies arise between the two parts, the provisions contained in Part 60 would be controlling. For example, proposed § 60.40 rather than § 16.22 would govern the initiation of due diligence hearings.

Proposed § 60.44 would also give all parties to a due diligence hearing the rights that are enjoyed by a single party under Part 16.

Proposed § 60.44 makes clear that the identical standards used in FDA's due diligence determinations will be applied to due diligence hearings and that the person requesting such a hearing has the burden of proof to show that the agency is in error.

4. Administrative Decision

Proposed § 60.46 describes the procedures for the decision the Commissioner must make after a due diligence hearing. The decision is termed a "due diligence redetermination" in the proposed regulations to distinguish this decision from the subject of the hearing, which is the agency's due diligence determination issued in response to a due diligence petition. The Commissioner may delegate both the authority to conduct the informal hearing and to make the redetermination to an official from within the Office of the Commissioner other than the Associate Commissioner for Health Affairs. See 21 CFR 5.27.

Proposed § 60.46 would implement the statutory requirement that the Commissioner notify PTO of the due diligence redetermination and publish the redetermination in the **Federal Register**. FDA also proposes to notify the person requesting the hearing, the petitioner, and the applicant of the redetermination by sending them copies of the notice sent to PTO.

V. Economic Assessment

The agency has considered the economic impact of this rule and the relationship of the requirements in this rule with Pub. L. 98–417. The patent extension provisions in Title II of Pub. L. 98–417 will result in economic consequences for affected patent holders and their potential competitors. However, the agency concludes that these impacts are directly attributable to the statute. This rule will affect neither the timing nor magnitude of these economic impacts. The procedural and interpretive nature of the rule will clarify and facilitate implementation of Title II, but this benefit by itself does not constitute a significant economic impact.

Thus, the agency concludes that this rule is not a "major rule" as defined by Executive Order 12291 and does not require a regulatory impact analysis. Similarly, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities, and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354).

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985; 50 FR 16636) 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.

VII. Paperwork Reduction Act of 1980

Sections 60.24(a), 60.30(a), and 60.40 of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information rquirements. Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim.

VIII. Request for Comments

Interested persons may, on or before October 9, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 60

Administrative practice and procedure, Drugs, Medical devices, Food additives, Color additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Drug Price Competition and Patent Term Restoration Act of 1984, it is proposed that new Part 60 be added to read as follows:

PART 60—PATENT TERM RESTORATION

Subpart A—General Provisions

Subpart B—Eligibility Assistance

Subpart C—Regulatory Review Period Determinations

Subpart D—Due Diligence Petitions

Subpart E—Due Diligence Hearings

Authority: Secs. 409, 505, 507, 515, 706, 52 Stat. 1052–1053 as amended, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 90 Stat. 552–559 (21 U.S.C. 348, 355, 357, 360e, 376); secs. 215, 301, 351, 354–360f, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 241, 262, 263b–263n); secs. 201, 202, 203, 98 Stat. 1599–1604 (35 U.S.C. 156, 271, 282); 21 CFR 5.10, 5.11.

Subpart A—General Provisions

§ 60.1 Scope.

(a) This part sets forth procedures and requirements for Food and Drug Administration review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to human drug products (as defined in 35 U.S.C. 156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act. Food and Drug Administration actions in this area include:

(1) Assisting the United States Patent and Trademark Office in determining eligiblity for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to the Food and Drug Administration's regulatory review period determinations; and

(4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to: (1) Facilitate concise determinations of patent term restoration eligibility and regulatory review period length, and (2) ensure that parties interested in due diligence challenges will have an opportunity to participate in that process, including informal hearings.

(b) The regulations are intended to complement those promulgated by the United States Patent and Trademark Office to implement those parts of the law which are under that agency's jurisdiction. These regulations shall be construed in light of these objectives.

§ 60.3 Definitions.

(a) The definitions contained in 35 U.S.C. 156 apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) "Act" means the Federal Food, Drug, and Cosmetic Act (secs. 201–901, 52 Stat. 1040 et seq. as amended (21 U.S.C. 301–392)).

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) "Applicant" means any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking patent term restoration.

(4) "Application" means an application for patent term restoration submitted under 35 U.S.C. 156.

(5) "Clinical investigation or study" means any experiment involving one or more human subjects in which a product subject to regulation under the act or the Public Health Service Act is used.

(6) "Color additive" means any substance that meets the definition in 21 U.S.C. 321(t) and which is subject to permanent listing under section 706 of the act.

(7) "Due diligence petition" means a petition submitted under § 60.30(a).

(8) "FDA" means the Food and Drug Administration.

(9) "Food additive" means any substance that meets the definition in 21 U.S.C. 321(s) and which is subject to approval under section 409 of the act.

(10) "Human drug product" means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(11) "Marketing applicant" means any person who submits an application for marketing approval by the FDA under:

(i) Section 505(b) or 507 of the act or section 351 of the Public Health Service Act (human drug products);

(ii) Section 515 of the act (medical devices); or

(iii) Section 409 or 706 of the act (food and color additives).

(12) "Marketing application" means an application for:

(i) Human drug products submitted under section 505(b) or 507 of the act or section 351 of the Public Health Service Act;

(ii) Medical devices submitted under section 515 of the act; or

(iii) Food and color additives submitted under section 409 or 706 of the act.

(13) "Medical device" means any article that meets the definition of 21 U.S.C. 321(h) and which is subject to premarket approval under section 515 of the act.

(14) "Product" means a human drug product, medical device, food additive, or color additive, as those terms are defined in this section.

(15) "PTO" means the United States Patent and Trademark Office.

Subpart B—Eligibility Assistance

§ 60.10 FDA assistance on eligibility.

(a) Upon written request from PTO, FDA will assist PTO in determining whether a patent related to a product is eligible for patent term restoration by:

(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product either:

(i) Under the provision of law under which the regulatory review period occurred; or

(ii) Under the process claimed in the patent when the patent claims a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product;

(3) Informing PTO whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing PTO with any other information relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

(b) FDA will notify PTO of its findings in writing, send a copy of this notification to the applicant, and file a copy of the notification in the docket established for the application in FDA's Dockets Management Branch (HFA–305), Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Subpart C—Regulatory Review Period Determinations

§ 60.20 FDA action on regulatory review period determinations.

(a) FDA will consult its records and experts to verify the dates contained in the application and to determine the length of the product's regulatory review period under § 60.22. The application must contain information relevant to the determination of the regulatory review period as stated in the "Guidelines for Extension of Patent Term Under 35 U.S.C. 156" published on October 9, 1984, in PTO's *Official Gazette,* and as required by 37 CFR Chapter I.

(b) After determining the length of the regulatory review period, FDA will notify PTO in writing of its determination, send a copy of this determination to the applicant, and file a copy of the determination in the docket established for the application in FDA's Dockets Management Branch (HFA–305), Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

(c) FDA will also publish the regulatory review period determination in the **Federal Register.** The notice will include the following:

(1) The name of the applicant;

(2) The trade name and generic name (if applicable) of the product;

(3) The patent number of the product seeking patent extension;

(4) The approved indications or uses for the product;

(5) An explanation of any discrepancies between the dates in the application and FDA records;

(6) As appropriate, an explanation that FDA has no record on which to review the date(s) contained in the application; and

(7) The regulatory review period determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

§ 60.22 Regulatory review period determinations.

In determining a product's regulatory review period, which consists of the sum of the lengths of a testing phase and an approval phase, FDA will review the information in each application using the following definitions of the testing phase and the approval phase for the class of products.

(a) For human drugs:

(1) The testing phase begins on the date an exemption under section 505(i) or 507(d) of the act becomes effective and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 or 507 of the act is initially submitted to FDA; and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service Act or section 505(b) or 507 of the act is initially submitted to FDA and ends on the date the application is approved.

(b) For food and color additives:

(1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test requesting the issuance of a regulation for use of the additive under section 409 or 706 of the act is initially submitted to FDA. For purposes of this part, a "major health or environmental" effects test may be any test which:

(i) Is reasonably related to the evaluation of the product's health effects, environmental effects, or both;

(ii) Produces data necessary for marketing approval; and

(iii) Is conducted over a period of not less than 6 months duration, excluding time required to analyze or evaluate test results.

(2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 706 of the act is initially submitted to FDA and ends upon whichever of the following occurs last:

(i) The regulation for the additive becomes effective; or

(ii) Objections filed against the regulation and resulting in a stay of its effectiveness are resolved and commercial marketing is permitted; or

(iii) Proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted.

(c) For medical devices:

(1) The testing phase begins on the date a clinical investigation on humans is begun and ends on the date an application for premarket approval of the device or a notice of completion of a product development protocol is initially submitted under section 515 of the act. For purposes of this part, a clinical investigation is considered to begin on whichever of the following dates applies:

(i) If an investigational device exemption (IDE) under section 520(g) of the act is required, the effective date of the exemption.

(ii) If an IDE is not required, but institutional review board (IRB) approval under section 520(g)(3) of the act is required, the IRB approval date.

(iii) If neither an IDE nor IRB approval is required, the date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device.

(2) The approval phase either:

(i) Begins on the date a premarket approval application for the device is initially submitted under section 515 of the act and ends on the date the application is approved; or

(ii) Begins on the date notice of completion of a product development protocol is initially submitted under section 515(f)(5) of the act and ends on the date the protocol is declared to be complete under section 515(f)(6) of the act.

(d) For purposes of determining the regulatory review period for any product, a marketing application or petition is "initially submitted" on the date it contains sufficient information to allow FDA to commence review of the application. A marketing application or petition is "approved" on the date FDA sends the applicant a letter informing it of the approval or, in the case of food and color additives, on the effective date of FDA's **Federal Register** final rule listing the additive for use.

§ 60.24 Revision of regulatory review period determination.

(a) Any person may request a revision of the regulatory review period determination within 60 days after its publication in the **Federal Register**. The request shall be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The request shall specify the following:

(1) The type of action requested;

(2) The identity of the product;

(3) The identity of the applicant;

(4) The FDA docket number; and

(5) The basis for the request for revision, including any documentary evidence.

(b) FDA will review the information contained in the request and, if necessary, give the applicant the opportunity to respond to the request for revision. A request for a revision is not equivalent to a due diligence petition under § 60.30 or a request for a hearing under § 60.40.

(c) FDA shall apply the provisions of § 60.22 in considering the request for a revision of the regulatory review period determination. When FDA revises its prior determination, FDA will notify PTO of the revision, publish its revision in the **Federal Register** including a statement giving the reasons for the revision, and send a copy of this notification to the applicant.

§ 60.26 Final action on regulatory review period determinations.

(a) FDA will consider a regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 60.30 unless FDA receives:

(1) New information from PTO records, FDA records, or FDA centers that affects the regulatory review period determination;

(2) A request under § 60.24 for revision of the regulatory review period determination;

(3) A due diligence petition filed under § 60.30; or

(4) A request for a hearing filed under § 60.40.

(b) Upon the expiration of the 180-day period for filing a due diligence petition or, if FDA has received a request for a revision, due diligence petition, or request for a hearing, upon resolution of the request for a revision, petition, or hearing, whichever is later, FDA will consider the regulatory review period determination to be final. FDA will notify PTO when the determination is final, send a copy of the notification to the applicant, and file a copy of the notification in the docket established for the application in FDA's Dockets Management Branch (HFA-305), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

§ 60.28 Time frame for determining regulatory review periods.

(a) FDA will determine the regulatory review period for each product within 30 days of the receipt of a written request from PTO for such a determination, accompanied by a copy of the patent term restoration application.

(b) FDA may extend the 30-day period if:

(1) A related FDA action that may affect the regulatory review period determination is pending; or

(2) PTO requests that FDA temporarily suspend the determination process; or

(3) PTO or FDA receives new information about the product that warrants an extension of the time required for the determination of the regulatory review period.

(c) This section does not apply to applications withdrawn by the applicant and applications that PTO determines are ineligible for patent term restoration.

Subpart D—Due Diligence Petitions

§ 60.30 Filing, format, and content of petitions.

(a) Any person may file a petition with FDA, no later than 180 days after the publication of a regulatory review period determination under § 60.20, that challenges FDA's determination by alleging that the applicant for patent term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

(b) The petition shall be filed in accordance with § 10.20, under the docket number of the **Federal Register** notice of the agency's regulatory review period determination, and shall be in the format specified in § 10.30. The petition shall contain the information specified in § 10.30 and any additional information required by this subpart. If any provision of § 10.20 or § 10.30 is inconsistent with any provision of this part, FDA will consider the petition in accordance with this part.

(c) The petition must claim that the applicant did not act with due diligence during some part of the regulatory review period and must set forth sufficient facts to merit an investigation by FDA of whether the applicant acted with due diligence.

(d) The petition shall contain a certification that the petitioner has served a true and complete copy of the petition upon the applicant by certified or registered mail (return receipt requested) or by personal delivery.

§ 60.32 Applicant response to petition.

(a) The applicant may file with FDA a written response to the petition no later than 10 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period.

§ 60.34 FDA action on petitions.

(a) Within 90 days after FDA receives a petition filed under § 60.30(a), the agency will either deny the petition under paragraphs (b) and (c) of this section or investigate and determine under § 60.36 whether the applicant acted with due diligence during the regulatory review period. FDA will publish its due diligence determination in the **Federal Register**, notify PTO of the due diligence determination in writing, and send copies of the notice to PTO, the applicant, and the petitioner.

(b) FDA may deny a due diligence petition without considering the merits of the petition if FDA determines that the petition is incomplete for any of the following reasons:

(1) The petition is not filed in accordance with § 10.20;

(2) The petition does not contain the information required by § 10.30;

(3) The petition fails to contain information or allegations upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period; or

(4) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition could not affect the maximum patent extension the applicant sought in the application.

(c) If the applicant acquiesces to a reduction in the regulatory review period determined under § 60.20 equal to the amount of time that the petitioner alleges the applicant did not act with due diligence, FDA may grant the petition without further action and without making specific findings on the issues presented in the petition. FDA will revise the regulatory review period determination, notify PTO in writing, and publish the revised determination in the **Federal Register** in accordance with paragraph (a) of this section. Any such notice will state that the revised determination is based on the acquiescence of the applicant and does not represent a finding by FDA that the applicant failed to act with due diligence during the regulatory review period.

§ 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. FDA will take into consideration all relevant factors affecting the applicant's actions. Relevant factors may include, but are not limited to, the following:

(1) The length of regulatory review periods for comparable products, where appropriate;

(2) Compliance or failure to comply with FDA requirements, including prescribed laws and regulations;

(3) Time solely attributable to FDA action as part of its regulatory review of the marketing application, not including enforcement or compliance action by the agency;

(4) Independent action by Federal, State, or local governments, not including FDA action, that interrupts testing, submission of data, or other activities required for regulatory review;

(5) Unavailability of any key person involved in the activities of the applicant during the regulatory review period;

(6) Physical destruction of essential testing facilities or essential data;

(7) Delay caused by financial considerations; and

(8) Implementation or failure to implement ordinary and necessary measures to minimize delay.

(b) For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearings

§ 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Dockets

Management Branch and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(c) The request shall state whether the requesting party seeks a hearing within 30 days or 60 days of FDA's receipt of the request.

§ 60.42 Notice of hearing.

The days before the hearing, FDA will notify the requesting party, the applicant, and the petitioner, orally or in writing, of the date, time, and location of the hearing. The agency will provide both the applicant and the petitioner with an opportunity to participate as a party in the hearing.

§ 60.44 Hearing procedure.

The due diligence hearing shall be conducted in accordance with this part, supplemented by those procedures in Part 16 that do not conflict with this part. During the due diligence hearing, the applicant and the petitioner shall enjoy all the rights and privileges accorded a person requesting a hearing under Part 16. The definition of due diligence set forth in § 60.36 will apply in the due diligence hearing. The party requesting the due diligence hearing shall have the burden of proof at the hearing.

§ 60.46 Administrative decision.

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the **Federal Register**, notify PTO of the redetermination, and send copies of the notice to PTO and to the parties to the hearing.

Dated: June 11, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

[FR Doc. 86-15631 Filed 7-10-86; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
July 11, 1986

Part IV

Environmental Protection Agency

40 CFR Parts 264 and 265

Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Liability Coverage; Interim Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 264 and 265

[SWH-FRL-3015-3]

Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Liability Coverage

AGENCY: Environmental Protection Agency.

ACTION: Interim final rule.

SUMMARY: On August 21, 1985 (50 FR 33902), the Environmental Protection Agency (EPA or the Agency) published a notice of proposed rulemaking to amend the financial responsibility requirements concerning liability coverage for owners and operators of hazardous waste treatment, storage, and disposal facilities (50 FR 33902). The proposal set forth several regulatory options under consideration by the Agency to provide relief for owners and operators who have encountered difficulties in obtaining insurance necessary to comply with these requirements. EPA is today amending these requirements in interim final form to allow use of one additional financial responsibility mechanism: A corporate guarantee. This action will facilitate greater compliance with the liability coverage requirements. The Agency is also requesting comments on the form of the guarantee.

EFFECTIVE DATE: These regulations shall become effective September 9, 1986.

ADDRESSES: The public must send an original and two copies of their comments on the interim final rule no later than August 11, 1986, to: EPA RCRA docket, (S–212) (WH–562) U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Place the docket #F–86–CGIF–FFFFF on your comments. The comments received plus the record supporting this rulemaking are available for public inspection at the docket room from 9:30 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. The public must make an appointment to review docket materials. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free, at (800) 424–9346 or at (202) 382–3000. For technical information, contact Carlos M. Lago, Office of Solid Waste (HW–562B), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 382–4780.

SUPPLEMENTARY INFORMATION:

I. Authority

This regulation is being promulgated under the authority of sections 2002(a), 3004, and 3005 of the Solid Waste Disposal Act; as amended by the Resource Conservation and Recovery Act, as amended [42 U.S.C. 6912(a), 6924, and 6925].

II. Background

A. Current Liability Coverage Requirements

Section 3004(a)(6) of the Resource Conservation and Recovery Act, as amended (RCRA), requires EPA to establish financial responsibility standards for owners and operators of hazardous waste management facilities as may be necessary or desirable to protect human health and the environment.

On April 16, 1982, EPA promulgated regulations requiring owners and operators to demonstrate liability coverage during the operating life of the facility for bodily injury and property damage to third parties resulting from accidental occurrences arising from facility operations (47 FR 16554). Under the liability coverage regulations (40 CFR 264.147 and 265.147), owners and operators of hazardous waste treatment, storage, and disposal facilities are required to demonstrate, on a per firm basis, liability coverage for sudden accidental occurrences in the amount of $1 million per occurrence and $2 million annual aggregate, exclusive of legal defense costs. Owners and operators of surface impoundments, landfills and land treatment facilities are also required to demonstrate, on a per firm basis, liability coverage for nonsudden accidental occurrences in the amount of $3 million per occurrence and $6 million annual aggregate, exclusive of legal defense costs. "First-dollar" coverage is required; that is, the amount of any deductible must be covered by the insurer, who may have a right of reimbursement of the deductible amount from the insured. Financial responsibility can be demonstrated through a financial test, liability insurance, or a combination of the two.

The requirements for coverage of sudden accidental occurrences became effective on July 15, 1982. The requirements for nonsudden accidental occurrences were phased in gradually according to annual dollar sales or revenue figures of the owner or operator. January 16, 1985 was the final phase-in date.

Congress has expressed its support for financial responsibility requirements in section 213 of the Hazardous and Solid Waste Amendments of 1984 (RCRA section 3005(e)). That section provides for the termination of interim status for all land disposal facilities by November 8, 1985, unless: (1) The owner or operator applies for a final determination regarding the issuance of a permit by that date and (2) certifies that the facility is in compliance with all applicable ground water monitoring and financial responsibility requirements for liability coverage, closure, and post-closure care. Prior to the enactment of HSWA, a facility's interim status could be terminated only when final administrative disposition of the permit application was made, or if the facility failed to furnish the necessary application information.

B. August 21, 1985, Proposed Rule

Some owners and operators have encountered difficulties in obtaining insurance necessary to comply with the liability coverage requirements. In the notice of proposed rulemaking published by EPA on August 21, 1985 (50 FR 33902), the Agency considered taking one or a combination of the following five regulatory actions in response to this problem:

(1) Maintain the existing requirements;

(2) Clarify the required scope of coverage and/or lower the required levels of coverage;

(3) Authorize other financial responsibility mechanisms;

(4) Authorize waivers; and

(5) Suspend or withdraw the liability coverage requirements.

The Agency has decided at this time to authorize owners and operators to use a corporate guarantee as another mechanism to comply with the liability coverage requirements. EPA is still considering the other options proposed in the August 21, 1985, Notice of Proposed Rulemaking, and will publish its decision in the future. Comments on the proposed rule that address the corporate guarantee are discussed in Section IV of this preamble. Comments on other issues raised by the proposal

will be addressed in subsequent publications.

III. Authorization of the Corporate Guarantee

To enable more firms to comply with the liability coverage required during a facility's operating life, the Agency has decided to revise 40 CFR 264.147, 264.151, and 265.147 to authorize, in addition to insurance and the financial test, the use of the corporate guarantee. The Agency believes this will provide owners and operators with greater flexibility while still ensuring that funds will be available to pay third-party liability claims. Use of the corporate guarantee is consistent with EPA's closure and post-closure financial responsibility regulations (40 CFR 264.143, 264.145, 265.143 and 265.145) and with Congressional intent. In the 1984 Hazardous and Solid Waste Amendments (HSWA), Congress provides that RCRA financial responsibility for liability insurance may be established by, among other options, guarantees and self-insurance (HSWA section 205; section 3004(t) of RCRA).

A corporate guarantee is a promise by one corporation to answer for the default of another. It is a collateral undertaking and presupposes another obligation which is identified in the guarantee. There is ordinarily a contract or other agreement between the principal (obligor) and a third party creating the primary obligations. The guarantee is then a contract between the principal and the guarantor, guaranteeing payment of the primary obligation. However, in the corporate guarantee that is the subject of today's rule, the obligation between the principal and third party will generally arise out of tort liability, not contract. In any case, if the principal defaults on the primary obligation, then the guarantor is liable to the third party on the obligation created by the guarantee. As provided in §§ 264.147(g)(1) and 265.147(g)(1) of today's rule, the guarantor must be the parent corporation of the owner or operator, directly owning at least 50 percent of the voting stock of the corporation that owns or operates the facility; the latter corporation is deemed a "subsidiary" of the parent corporation.

The Agency has decided to allow use of the corporate guarantee only if the guarantor is the parent corporation of the owner or operator because it believes such a guarantee is more likely to be enforceable under state law, and because the parent corporation is interested in its subsidiaries' performance, and is in a better position than other corporate entities to ensure that the facilities in question are being operated in conformance with EPA regulations.

The corporate guarantee that is the subject of today's rule differs from the corporate guarantee for closure or post-closure care in several ways. First, and most important, the guarantee is not made to the Environmental Protection Agency, as obligee. Instead, the corporate guarantee for liability coverage is made by the corporate parent on behalf of the owner or operator "to any and all third parties who have sustained or may sustain bodily injury or property damage caused by [sudden and/or nonsudden] accidental occurrences arising from operations of the facilities covered by [the] guarantee". Unlike the corporate guarantee for closure or post-closure care, EPA cannot take action to enforce the terms of the corporate guarantee for liability coverage. Action to notify the corporate guarantor of an obligation to pay under the terms of the guarantee will have to be taken by injured parties who are covered by the guarantee.

Second, the Agency has modified the cancellation provisions. The guarantee for closure and/or post-closure care may be terminated 120 days or later, after notice is provided to the EPA Regional Administrator. In that case, the guarantor is responsible for providing alternative financial assurance if the owner or operator fails to provide such assurance. Today's rule, however, provides guarantor cannot terminate a liability coverage guarantee unless and until the owner or operator obtains alternative liability coverage that the Regional Administrator(s) for the Region(s) in which the facility(ies) is (are) located approve(s). We believe that this formulation will better provide continued assurance of financial responsibility. In addition, while the Regional Administrator can require an owner or operator to undertake closer or post-closure actions, and may decide to invoke that authority upon receipt of a cancellation notice, no comparable authority exists for third-party liability.

Finally, the Agency has added a requirement, not found in the corporate guarantee for closure or post-closure care, that the guarantee is to be interpreted and enforced in accordance with the laws of the State of incorporation of the guarantor. This clause is intended to operate in conjunction with the regulatory requirement in § 264.147(g)(2) to ensure that the corporate guarantee for liability is valid and enforceable under the relevant State law. Section 264.147(g)(2) provides that the corporate guarantee may be used to satisfy the liability coverage requirements only if the Attorney General(s) or insurance commissioner(s) of the State(s) in which the guarantor is incorporated and the State(s) in which the facility(ies) covered by the guarantee is (are) located have submitted a written statement to EPA that a corporate guarantee executed as required is a legally valid and enforceable obligation in that State. The Agency expects in this way to ensure that State limitations on the powers of corporations to undertake guarantee obligations will not affect the operation of the corporate guarantee for liability.

Because EPA recognizes that a subsidiary's assets and liabilities are usually consolidated into the balance sheet of parent corporations, the Agency has decided not to allow a corporate subsidiary to use the financial test in combination with the corporate guarantee. However, an owner or operator may use insurance in combination with either the financial test or the corporate guarantee to comply with the liability requirements (§ 264.147(a)(3) and § 265.147(a)(3)).

EPA has decided to allow use of the corporate guarantee because it may provide relief for some owners and operators who are unable to obtain insurance. However, the Agency has concerns about the enforceability of the guarantee under State insurance law. This is a major reason why the guarantee is restricted to parents. In addition, because the validity of the corporate guarantee will depend on applicable state law, the guarantee will be allowed only for facilities in States where the State Attorney General or State insurance commissioner has certified to EPA that the guarantee is fully valid and enforceable by third-parties who are injured by accidents arising from the operations of the facility involved. EPA has sent requests to the Attorney General in each State for an opinion on this subject. A list of non-authorized States where the parent corporate guarantee is fully valid and enforceable will then be compiled by the Agency to be published in the **Federal Register** in the near future.

IV. Summary of and Response to Comments on Corporate Guarantee

In the August 21, 1985 notice of proposed rulemaking, the Agency requested comments on whether the corporate guarantee should be authorized as an alternative mechanism for demonstrating financial assurance for liability coverage. The Agency previously considered authorizing the corporate guarantee as an alternative

financial assurance mechanism for liability coverage, but had major questions about the validity and enforceability of such an arrangement, especially with respect to State insurance laws (47 FR 16547 (April 16, 1982)).

The Agency requested comments on the potential advantages and disadvantages of authorizing owners and operators to use a corporate guarantee to demonstrate financial assurance for liability coverage. In particular, comments were requested on the validity and the enforceability of this mechanism with respect to State laws. Most commenters on the proposed rule strongly endorsed the corporate guarantee as an additional financial responsibility alternative for satisfying liability coverage requirements.

Commenters stated that the corporate guarantee is a common commercial instrument and that most States' general corporation laws authorize corporations to enter into guarantee contracts. The commenters who provided information about State insurance laws generally stated that the corporate guarantee for liability coverage would be valid under their State's statutes. For example, one commenter from North Carolina said that initial research showed that the corporate guarantee would be a valid and enforceable obligation under North Carolina law. In addition, a commenter noted that Colorado and Montana currently allow the corporate guarantee for liability coverage. One commenter in Kentucky said that normal transporters, including hazardous waste transporters, are allowed to self-insure through their parent corporations to satisfy the Kentucky Department of Transportation's requirements for transporters.

Several commenters stated that if a corporate guarantee were allowed as an alternate mechanism, they would take advantage of that option. One commenter suggested that allowing the corporate guarantee to demonstrate financial assurance for liability coverage could increase compliance with the liability coverage requirements. Louisiana strongly supported the use of the corporate guarantee, stating that preliminary analysis showed that it would allow medium-sized companies and commercial hazardous waste disposers to comply with the liability coverage rules.

Several commenters noted that use of the corporate guarantee might simplify the task of preparing financial assurance documentation, which would result in increased compliance with the regulations. Because many subsidiaries consolidate their financial statements with parent corporations, they do not have separately audited financial statements. According to some commenters, requiring each subsidiary to comply with the financial test greatly increases the cost of compliance and generates significant quantities of duplicate documentation.

Commenters also offered various other arguments in support of use of the corporate guarantee for liability coverage. Several said that the guarantee is consistent with existing business practices. Financial institutions have used corporate guarantees to assure repayment of debt by a subsidiary. The commenters believed that corporate guarantees would provide a cost-effective alternative to obtaining insurance. One commenter suggested that the corporate guarantee would better achieve the goal of the liability coverage regulations, because, unlike many insurance policies, it would provide financial assurance for liability exposure from pre-existing contamination.

Commenters who opposed use of the corporate guarantee as an alternative mechanism for demonstrating financial assurance for liability coverage made several arguments. First, some commenters were concerned that the guarantee would not be valid or enforceable. The Agency shares that concern, and is thus requiring that before a corporate guarantee can be used to demonstrate financial assurance, the State Attorney General(s) or insurance commissioner(s) in the State(s) where the guarantor is incorporated and where the facility(ies) is (are) located must issue a written statement that under the laws of that (these) State(s) such a guarantee is valid and enforceable.

Second, some commenters suggested that the corporate guarantee would not be an effective financial assurance mechanism in the long run because parent corporations eventually would find themselves in the situation currently faced by some private insurance companies, that is, subject to extensive litigation and clean-up expenses. The Agnecy believes that a parent will have a strong interest in ensuring that a guaranteed subsidiary has sufficient pollution monitoring and safety measures to prevent and minimize accidential releases and third party damages from occurring at the subsidiaries' TSDFs. In addition, where third party damages occur, the parent guarantor's financial liability will be limited to the amount of the guarantee, exclusive of legal defense costs.

One commenter asked whether it was advisable for a corporate parent to advance a guarantee to a company that cannot obtain liability insurance, and wondered if that opened the door to a lawsuit against the parent's directors and officers. Parent corporations should use good judgment about the guarantees that they provide to subsidiaries. Nevertheless, the inability of a subsidiary to obtain liability insurance is not necessarily an indication that the subsidiary's facilities are likely to cause damages to third parties and should be closed.

Commenters argued that a parent corporation might guarantee subsidiaries for which the parent did not have the funding to provide liability coverage. The Agency disagrees. The requirement that a parent corporation seeking to provide a corporate guarantee must satisfy the requirements of the financial test will provide assurance that the parent corporation has sufficient financial strength to issue the guarantee.

Commenters who were concerned about the November 8, 1985, deadline for certifying compliance with the liability coverage requirements suggested combining the corporate guarantee with another alternative, such as waivers. Commenters suggested that the Agency should grant waivers to those facility owners and operators who could not certify compliance with the financial responsibility requirements for liability coverage, closure, and post-closure care on November 8, but who could use the corporate guarantee once it is authorized. The Agency cannot adopt this suggestion. Under section 3005(e) of RCRA, facilities who did not certify compliance with the liability coverage regulations by November 8, 1985, lost interim status. The Agency does not have authority to nullify that event.

One commenter suggested that the following concerns should be addressed in developing any corporate guarantee: (1) Whether funds would be required to be set aside or otherwise available for third party claims; and (2) whether, because of the complexity of the guarantee, third parties would be inhibited from obtaining access to "legitimate" compensation funds or whether inordinate time and resources would be required to enforce the guarantee. The Agency has considered these issues in promulgating the corporate guarantee. Although the guarantor is not required to set aside funds for third party compensation, it must pass the financial test and thereby demonstrate that it has sufficient funds to implement its guarantee, if necessary. Second, as discussed in detail in Section

III, the Agency has attempted to design the corporate guarantee to allow for the easiest possible enforcement by third parties.

In summary, the Agency disagrees with those commenters who opposed use of the corporate guarantee as an alternative mechanism. Although certain State laws may not authorize use of the corporate guarantee for liability coverage, the Agency believes that in most States the guarantee will be valid and enforceable. Under a corporate guarantee, the parent corporation guarantees its subsidiary's obligations and therefore has a direct financial stake in its subsidiaries' actions. The strict requirements of the financial test will deter a parent corporation from issuing a guarantee for a subsidiary when it does not have adequate financial strength to assure the availability of funds for third party liability claims. The Agency believes that expanding the number of available options is desirable, given the present state of the insurance market and the high level of assurance provided by the corporate guarantee.

V. Effective Date

This regulation is being published in "interim final form". This means that although the regulation will be effective in 60 days, the Agency solicits comments on the regulation (in particular the form of the corporate guarantee), and may modify it in response to additional public comment.

Section 3010(b) of RCRA provides that EPA's hazardous waste regulations and revisions thereto generally take effect six months after their promulgation. The purpose of this requirement is to allow sufficient lead time for the regulated community to prepare to comply with major new regulatory requirements. The statute allows for a shorter period prior to the effective date, however, for "good cause" (among other reasons), which the Agency believes exists here. The Agency believes that an effective date six months after promulgation for the amendment promulgated today, would cause substantial and unnecessary disruption in the implementation of the existing regulations and would be contrary to the interest of the regulated community and the public.

Today's amendment adopts the corporate guarantee as another mechanism for complying with third-party liability coverage requirements and thus makes it easier for some owners and operators to act in accordance with the RCRA liability coverage regulations. The Agency believes that it makes little sense to delay needed relief to owners or operators by an additional four months. However, because the Agency may wish to revise the form of the guarantee on the basis of public comment, the amendments to §§ 264.147, 264.151 and 265.147 promulgated in this rulemaking action will not be effective until 60 days from the date of this **Federal Register** notice.

VI. State Authority

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, EPA retains enforcement authority under sections 3008, 7003, and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Today's announcement will be automatically applicable only in those States that do not have final authorization. In authorized States, the requirements will not be applicable unless and until the State revises its program to adopt equivalent requirements under State law.

It should be noted that authorized States are required to modify their programs only when EPA promulgates Federal standards that are more stringent or broader in scope than the existing Federal standards. For those Federal program changes that are less stringent or reduce the scope of the Federal program, States are not required to modify their programs. This is a result of section 3009 of RCRA, which allows States to impose standards in addition to those in the Federal program.

The standards promulgated today are considered to be less stringent than the existing Federal requirements. Therefore, authorized States are not required to modify their programs to adopt requirements equivalent or substantially equivalent to the provisions listed above.

VII. Request for Public Comment

Although the use of a corporate guarantee was proposed August 21, 1985, the Agency did not specify what form the guarantee would take. We believe that the guarantee form included in § 264.151 of today's rule will generally be valid and enforceable. At a minimum, section 3004(t) of RCRA provides for a right of direct action against guarantors in the event of bankruptcy of the owner or operator, or if a court's jurisdiction cannot be obtained over an owner or operator likely to be insolvent at the time of judgment. Moreover, we believe that a right of action under the guarantee set forth in today's rule will lie against the guarantor whenever a judgment has been obtained against the owner or operator or a settlement agreement has been executed.

However, due to the unusual nature of the guarantee (i.e., it is a general guarantee designed to assure payment of tortious, rather than contractual, obligations to unidentified third parties), the Agency would appreciate public comments *on the form itself.* In particular, the Agency requests comments on whether any modifications to the form would be desirable to facilitate claims by injured third parties against the guarantor. We do *not* solicit comments on the § 264.147 and § 265.147 requirements themselves.

Two copies of all comments should be sent, no later than 30 days after the date of this notice to: EPA public docket, room S–212, U.S. EPA, 401 M Street SW., Washington, DC 20460, where they may be inspected by all interested parties.

VIII. Executive Order 12291

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291. The regulatory amendments being considered today to the liability coverage requirements are not "major rules". The options under consideration will not likely result in a significant increase in costs (but are likely to decrease costs) and thus are not a major rule; no Regulatory Impact Analysis has been prepared.

IX. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number 2050–0036.

X. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1950 (5 U.S.C. 601 *et seq.*), Federal Agencies must, in developing regulations, analyze their impact on small entities (small businesses, small government jurisdictions, and small organizations). The option under consideration relaxes the existing insurance requirements and thus commonly reduces costs associated with compliance.

Accordingly, I certify that this proposed regulation will not have a significant impact on a substantial number of small entities.

XI. Supporting Documents

Supporting documents available for this interim final rule include comments on the August 21, 1985 proposed rule, summary of the comments, and background documents on the financial test for liability coverage. In addition, background documents prepared for previous financial assurance regulations are also available.

All of these supporting materials are available for review in the EPA public docket (RCRA docket #F-86-CGIF-FFFFF), Room S-212, Waterside Mall, 401 M Street SW., Washington, DC 20460.

List of Subjects

40 CFR Part 264

Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Hazardous waste, Insurance, Packaging and containers, reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

Dated: July 3, 1986.

Lee M. Thomas,

Administrator.

For reasons set out in the preamble, Title 40 of the Code of Federal Regulations is amended as follows:

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES: LIABILITY COVERAGE

40 CFR Part 264 is amended as follows:

1. The authority citation for Part 264 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004 and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6924, and 6925).

2. In § 264.147, paragraph (g) is redesignated as paragraphs (h), paragraph (a)(3), (b)(2), (a)(2), and (b)(3) are revised, and a new paragraph (g) is added, to read as follows:

§ 264.147 Liability requirements.

(a) * * *

(2) An owner operator may meet the requirements of this section by passing a financial test or using the corporate guarantee for liability coverage as specified in paragraph (g) of this section.

(3) An owner or operator may demonstrate the required liability coverage through use of the financial test, insurance, the corporate guarantee, a combination of the financial test and insurance, or a combination of the corporate guarantee and insurance. The amount of coverage demonstrated must total at least the minimum amounts required by this paragraph.

(b) * * *

(2) An owner or operator may meet the requirements of this section by passing a financial test or using the corporate guarantee for liability coverage as specified in paragraphs (f) and (g) of this section.

(3) An owner or operator may demonstrate the required liability coverage through use of the financial test, insurance, the corporate guarantee, a combination of the financial test and insurance, or a combination of the corporate guarantee and insurance. The amounts of coverage demonstrated must total at least the minimum amounts required by this paragraph.

* * * * *

(g) Corporate guarantee for liability coverage.

(1) Subject to subparagraph (2), an owner or operator may meet the requirements of this section by obtaining a written guarantee, hereinafter referred to as "corporate guarantee." The guarantor must be the parent corporation of the owner or operator. The guarantee must meet the requirements for owners or operators in paragraphs (f)(1) through (7) of this section. The wording of the corporate guarantee must be identical to the wording specified in § 264.151(h)(2). A certified copy of the corporate guarantee must accompany the items sent to the Regional Administrator as specified in paragraph (f)(3) of this section. The terms of the corporate guarantee must provide that:

(i) If the owner or operator fails to satisfy a judgment based on a determination of liability for bodily injury or property damage to third parties caused by sudden or nonsudden accidental occurrences (or both as the case may be), arising from the operation of facilities covered by this corporate guarantee, or fails to pay an amount agreed to in settlement of claims arising from or alleged to arise from such injury or damage, the guarantor will do so up to the limits of coverage.

(ii) The corporate guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the owner or operator and to the Regional Administrator(s). This guarantee may not be terminated unless and until the EPA Regional Administrator(s) approve(s) alternate liability coverage complying with section 264.147 and/or 265.147.

(2) A corporate guarantee may be used to satisfy the requirements of this section only if the Attorney General(s) or insurance commissioner(s) of the State in which the guarantor is incorporated *and* the State(s) in which the facility(ies) covered by the guarantee is (are) located has (have) submitted a written statement to EPA that a corporate guarantee executed as described in this section and Section 264.151(h)(2) is a legally valid and enforceable obligation in that State.

* * * * *

3. In § 264.151, paragraph (g) is revised to read as follows:

§ 264.151 Wording of the instruments.

* * * * *

(g) A letter from the chief financial officer, as specified in § 264.147(f) or § 265.147(f) of this chapter, must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Letter From Chief Financial Officer

[Address to Regional Administrator of every Region in which facilities for which financial responsibility is to be demonstrated through the financial test are located.]

I am the chief financial officer of [firm's name and address]. This letter is in support of the use of the financial test to demonstrate financial responsibility for liability coverage [insert "and closure and/or post-closure care" if applicable] as specified in Subpart H of 40 CFR Parts 264 and 265.

[Fill out the following paragraphs regarding facilities and liability coverage. If there are no facilities that belong in a particular paragraph, write "None" in the space indicated. For each facility, include its EPA Identification Number, name, and address.]

The firm identified above is the owner or operator of the following facilities for which liability coverage for [insert "sudden" or "nonsudden" or "both sudden and nonsudden"] accidental occurrences is being demonstrated through the financial test specified in Subpart H of 40 CFR Parts 264 and 265:———.

The firm identified above guarantees, through the corporate guarantee specified in Subpart H of 40 CFR Parts 264 and 265, liability coverage for [insert "sudden" or "nonsudden" or "both sudden and nonsudden"] accidental occurrences at the following facilities owned or operated by the following subsidiaries of the firm:———.

[If you are using the financial test to demonstrate coverage of both liability and closure and post-closure care, fill in the following four paragraphs regarding facilities and associated closure and post-closure cost estimates. If there are no facilities that belong in a particular paragraph, write "None" in the space indicated. For each facility, include its EPA Identification Number, name, address, and current closure and/or post-closure cost estimates. Identify each cost estimate as to whether it is for closure or post-closure care.]

1. The firm identified above owns or operates the following facilities for which financial assurance for closure or post-closure care is demonstrated through the financial test specified in Subpart H of 40 CFR Parts 264 and 265. The current closure and/or post-closure cost estimates covered by the test are shown for each facility:_____.

2. The firm identified above guarantees, through the corporate guarantee specified in Subpart H of 40 CFR Parts 264 and 265, the closure and post-closure care of the following facilities owned or operated by its subsidiaries. The current cost estimates for the closure or post-closure care so guaranteed are shown for each facility:_____.

3. In States where EPA is not administering the financial requirements of Subpart H of 40 CFR Parts 264 and 265, this firm is demonstrating financial assurance for the closure or post-closure care of the following facilities through the use of a test equivalent or substantially equivalent to the financial test specified in Subpart H of 40 CFR Parts 264 and 265. The current closure or post-closure cost estimates covered by such a test are shown for each facility:_____.

4. The firm identified above owns or operates the following hazardous waste management facilities for which financial assurance for closure or, if a disposal facility, post-closure care, is not demonstrated either to EPA or a State through the financial test or any other financial assurance mechanisms specified in Subpart H of 40 CFR Parts 264 and 265 or equivalent or substantially equivalent State mechanisms. The current closure and/or post-closure cost estimates not covered by such financial assurance are shown for each facility:_____.

5. This firm is the owner or operator of the following UIC facilities for which financial assurance for plugging and abandonment is required under Part 144. The current closure cost estimates as required by 40 CFR 144.62 are shown for each facility:_____.

This firm [insert "is required" or "is not required"] to file a Form 10K with the Securities and Exchange Commission (SEC) for the latest fiscal year.

The fiscal year of this form ends on [month, day]. The figures for the following items marked with an asterisk are derived from this firm's independently audited, year-end financial statements for the latest completed fiscal year, ended [date].

* * * * *

4. In § 264.151, introductory paragraph (h) is redesignated as paragraph (h)(1) and a new paragraph (h)(2) is added to read as follows:

§ 264.151 Wording of the instruments.

* * * * *

(h)(2) A corporate guarantee, as specified in § 264.147(g) or § 265.147(g) of this Chapter, must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Corporate Guarantee for Liability Coverage

Guarantee made this [date] by [name of guaranteeing entity], a business corporation organized under the laws of the State of [insert name of State], herein referred to as guarantor, on behalf of our subsidiary [owner or operator] of [business address], to any and all third parties who have sustained or may sustain bodily injury or property damage caused by [sudden and/or nonsudden] accidental occurrences arising from operation of the facility(ies) covered by this guarantee.

Recitals

1. Guarantor meets or exceeds the financial test criteria and agrees to comply with the reporting requirements for guarantors as specified in 40 CFR 264.147(g) and 265.147(g).

2. [Owner or operator] owns or operates the following hazardous waste management facility(ies) covered by this guarantee: [List for each facility: EPA Identification Number, name, and address.] This corporate guarantee satisfies RCRA third-party liability requirements for [insert "sudden" or "nonsudden" or "both sudden and nonsudden"] accidental occurrences in above-named owner or operator facilities for [insert dollar amount] of coverage.

3. For value received from [owner or operator], guarantor gurarantees to any and all third parties who have sustained or may sustain bodily injury or property damage caused by [sudden and/or nonsudden] accidental occurrences arising from operations of the facility(ies) covered by this guarantee that in the event that [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [sudden and/or nonsudden] acidential occurrences, arising from the operation of the above-named facilities, or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor will satisfy such judgment(s), award(s), or settlement agreement(s) up to the limits of coverage identified above.

4. Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 90 days, by certified mail, notice to the EPA Regional Administrator(s) for the Region(s) in which the facility(ies) is (are) located and to [owner or operator] that he intends to provide alternate liability coverage as specified in 40 CFR 264.147 and 265.147, as applicable, in the name of [owner or operator]. Within 120 days after the end of such fiscal year, the guarantor shall establish such liability coverage unless [owner or operator] has done so.

5. The guarantor agrees to notify the EPA Regional Administrator by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming guarantor as debtor, within 10 days after commencement of the proceeding.

6. Guarantor agrees that within 30 days after being notified by an EPA Regional Administrator of a determination that guarantor no longer meets the financial test criteria or that he is disallowed from continuing as a guarantor, he shall establish alternate liability coverage as specified in 40 CFR 264.147 or 265.147 in the name of [owner or operator], unless [owner or operator] has done so.

7. Guarantor reserves the right to modify this agreement to take into account amendment or modification of the liability requirements set by 40 CFR 264.147 and 265.147, provided that such modification shall become effective only if a Regional Administrator does not disapprove the modification within 30 days of receipt of notification of the modification.

8. Guarantor agrees to remain bound under this guarantee for so long as [owner or operator] must comply with the applicable requirements of 40 CFR 264.147 and 265.147 for the above-listed facility(ies), except as provided in paragraph 9 of this agreement.

9. Guarantor may terminate this guarantee by sending notice by certified mail to the EPA Regional Administrator(s) for the Region(s) in which the facility(ies) is (are) located and to [owner or operator], provided that this gurarantee may not be terminated unless and until [the owner or operator] obtains, and the EPA Regional Administrator(s) approve(s) alternate liability coverage complying with 40 CFR 264.147 and/or 265.147.

10. This guarantee is to be interpreted and enforced in accordance with the laws of [State of incorporation of guarantor].

11. Guarantor hereby expressly waives notice of acceptance of this guarantee by any party.

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 264.151(h)(2).

Effective date: _____

[Name of guarantor]

[Authorized signature for guarantor]

[Name of person signing]

[Title of person signing]

Signature of witness or notary:

---

* * * * *

PART 265—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES: LIABILITY COVERAGE

40 CFR Part 265 is amended as follows:

1. The authority citation for Part 265 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004 and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6908, 6912(a), 6924 and 6925).

2. In § 265.147, paragraph (g) is redesignated as paragraph (h), paragraphs (a)(2), (a)(3), (b)(2), and (b)(3) are revised, and a new paragraph (g) is added, to read as follows:

§ 265.147 Liability requirements.

(a) * * *

(2) An owner or operator may meet the requirements of this section by passing a financial test or using the corporate guarantee for liability coverage as specified in paragraph (g) of this section.

(3) An owner or operator may demonstrate the required liability coverage through use of the financial test, insurance, the corporate guarantee, a combination of the financial test and insurance, or a combination of the corporate guarantee and insurance. The amounts of coverage demonstrated must total at least the minimum amounts required by this paragraph.

(b) * * *

(2) An owner or operator may meet the requirements of this section by passing a financial test or using the corporate guarantee for liability coverage as specified in paragraphs (f) and (g) of this section.

(3) An owner or operator may demonstrate the required liability coverage through use of the financial test, insurance, the corporate guarantee, a combination of the financial test and insurance, or a combination of the corporate guarantee and insurance. The amounts of coverage demonstrated must total at least the minimum amounts required by this paragraph.

* * * * *

(g) Corporate guarantee for liability coverage.

(1) Subject to subparagraph (2), an owner or operator may meet the requirements of this section by obtaining a written guarantee, hereinafter referred to as "corporate guarantee." The guarantor must be the parent corporation of the owner or operator. The guarantor must meet the requirements for owners or operators in paragraphs (f)(1) through (7) of this section. The wording of the corporate guarantee must be identical to the wording specified in § 264.151(h)(2). A certified copy of the corporate guarantee must accompany the items sent to the Regional Administrator as specified in paragraph (f)(3) of this section. The terms of the corporate guarantee must provide that:

(i) If the owner or operator fails to satisfy a judgment based on a determination of liability for bodily injury or property damage to third parties caused by sudden or nonsudden accidental occurrences (or both as the case may be), arising from the operation of facilities covered by this corporate guarantee, or fails to pay an amount agreed to in settlement of claims arising from or alleged to arise from such injury or damage, the guarantor will do so up to the limits of coverage.

(ii) The corporate guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the owner or operator and to the Regional Administrator(s). This guarantee may not be terminated unless and until the EPA Regional Administrator(s) approve(s) alternate liability coverage complying with § 264.147 and/or 265.147.

(2) A corporate guarantee may be used to satisfy the requirements of this section only if the Attorney General(s) or insurance commissioner(s) of the State in which the guarantor is incorporated *and* the State(s) in which the facility(ies) covered by the guarantee is (are) located has (have) submitted a written statement to EPA that a corporate guarantee executed as described in this section and Section 264.151(h)(2) is a legally valid and enforceable obligation in that State.

* * * * *

[FR Doc. 86-15673 Filed 7-10-86; 8:45 am]

BILLING CODE 6560-50-M