and has an indirect cost rate that has been approved by a Federal agency, the basis for that rate together with a copy of the letter or other official document stating that it has been approved should be attached.

If funds from other sources have been requested either as match or to support other aspects of the project, the source, current status of the request, and anticipated decision date must be provided.

Form D

State Justice Institute

Assurances

The applicant hereby assures and certifies that it possesses legal authority to apply for the award, and that if funds are awarded by the State Justice Institute pursuant to this application, it will comply with all applicable provisions of law and the regulations, policies, guidelines and requirements of the Institute as they relate to the acceptance and use of Institute funds pursuant to this application. The applicant further assures and certifies with respect to this application, that:

1. No person will, on the basis of race, sex, national origin, disability, color, or creed be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination under any program or activity supported by Institute funds; and that the applicant will immediately take any measures necessary to effectuate this assurance;

2. In accordance with 42 U.S.C. 10706(a), funds awarded to the applicant by the Institute will not be used, directly or indirectly, to influence the issuance, amendment, or revocation of any Executive order or similar promulgation by Federal, State or local agencies; to influence the passage or defeat of any legislation or constitutional amendment by any Federal, State or local legislative body;

3. In accordance with 42 U.S.C. 10706(a) and 10707(c):

a. It will not contribute or make available Institute funds, project personnel, or equipment to any political party or association, to the campaign of any candidate for public or party office, or to influence the passage or defeat of any ballot measure, initiative, or referendum;

b. No officer or employee of the applicant will intentionally identify the Institute or the applicant with any partisan or nonpartisan political activity or the campaign of any candidate for public or party office; and,

c. No officer or employee of the applicant will engage in partisan political activity while engaged in work supported in whole or in part by the Institute;

4. In accordance with 42 U.S.C. 10706(b), no funds awarded by the Institute will be used to support or conduct training programs for the purpose of advocating particular nonjudicial public policies or encouraging nonjudicial political activities.

5. In accordance with 42 U.S.C. 10706(d), no funds awarded by the Institute will be used to supplant State or local funds supporting a program or activity; to construct court facilities or structures, except to remodel existing facilities or to demonstrate new architectural or technological techniques, or to provide temporary facilities for new personnel or for personnel involved in a demonstration or experimental program; or to solely purchase equipment for a court system.

6. It will provide for an annual fiscal audit of the project.

7. It will give the Institute, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award.

8. Research or statistical information that is furnished during the course of the project and that is identifiable to any specific private person, will not be used or revealed for any purpose other than the purpose for which it was obtained, nor will such information or copies thereof be offered as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding without the consent of the person who furnished the information.

9. All products prepared as the result of the project will be originally-developed material unless otherwise specifically provided for in the award document; and that material not originally developed that is included in such products must be properly identified, whether the material is in a verbatim or extensive paraphrase format.

10. The following statement will be prominently displayed on all products prepared as a result of the project:

This [document, film, videotape, etc.] was developed under a [grant, cooperative agreement, contract] from the State Justice Institute. Points of view expressed herein are those of the [author(s), filmmakers, etc.] and do not necessarily represent the official position or policies of the State Justice Institute.

11. Except as otherwise provided in the terms and conditions of an Institute award, the recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of an Institute supported project, but the Institute shall reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the materials for purposes consistent with the State Justice Institute Act.

12. It will submit quarterly progress and financial reports within 30 days of the close of each calendar quarter during the funding period; that progress reports will include a narrative description of project activities during the calendar quarter, the relationship between those activities and the task schedule and objectives set forth in the approved application or an approved adjustment thereto, any significant problem areas that have developed and how they will be resolved, and the activities scheduled during the next reporting period; and that financial reports will contain the information requested on the financial report form included in the award documents.

13. At the conclusion of the project, title to all expendable and nonexpendable personal property purchased with Institute funds shall vest in the court, organization, or individual that purchased the property if certification is made to the Institute that the property will continue to be used for the authorized purposes of the Institute-funded project or other purposes consistent with the State Justice Institute Act, as approved by the Institute. If such certification is not made or the Institute disapproves such certification, title to all such property with an aggregate or individual value of $1,000 or more shall vest in the Institute, which will direct the disposition of the property.

14. The person signing this application is authorized to do so on behalf of the applicant and to obligate the applicant to comply with the assurances enumerated above.

David I. Tevelin,

Executive Director.

[FR Doc. 87-10476 Filed 5-8-87; 8:45 am]

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Monday
May 11, 1987

Part VI

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 700, 701, 785, and 827
Permanent Regulatory Programs; Definitions; Requirements for Permits for Special Categories of Mining; Coal Preparation Plants: Performance Standards; Final Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 700, 701, 785, and 827

Permanent Regulatory Programs; Definitions; Requirements for Permits for Special Categories of Mining; Coal Preparation Plants: Performance Standards

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) is amending its regulations applicable to coal preparation plants. This action is taken in compliance with the District Court for the District of Columbia's July 6, 1984, ruling in *In Re: Permanent Surface Mining Regulation Litigation (II)* and supersedes an interim final rulemaking from July 10, 1985. The revised regulations (1) bring additional coal preparation plants under the permanent program regulations of the Surface Mining Control and Reclamation Act of 1977 (the Act); (2) allow persons operating coal preparation plants not previously subject to OSMRE rules a certain period of time to obtain the permit required as a result of the Court ruling; and (3) establish performance standards for such plants or facilities.

DATE: This rule is effective on June 10, 1987.

FOR FURTHER INFORMATION CONTACT: Raymond Aufmuth, Division of State Program Assistance, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Washington, DC 20240: Telephone: (202) 343–5843.

SUPPLEMENTARY INFORMATION:

I. Background

The Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201 *et seq.*, sets forth general regulatory requirements governing certain activities associated with coal mining. One of those activities is the preparation and processing of coal.

In September 1977, OSMRE proposed interim program regulations which defined "Coal preparation" in very narrow terms, which meant the treatment of coal to improve its quality and refers to the removal of impurities and the sizing of coal to meet market specifications (42 FR 44956).

In December of 1977, OSMRE published the final interim program which, in response to numerous comments, added a definition of "waste" which included materials wasted or otherwise separated from the product coal and retained separation of impurities as a key element in the definition of preparation. (42 FR 62646).

The proposed permanent program rules published in September 1978 included a definition of the term "coal processing waste" which superseded the definition of "waste" above. It was intended to differentiate spoil, overburden and solid waste from the materials subject to the standards found at 30 CFR 816.81–88/817.81–88, "coal mine waste" (43 FR 41688). These rules also proposed a definition of "coal processing plant" which contained separation of impurities as an integral part of the definition (43 FR 41804).

In March 1979, the final permanent program preamble, in a discussion explaining the authority of OSMRE and the states, included ". . . . coal processing plants no matter where located." (44 FR 15095) OSMRE regulated these facilities because associated with coal processing plants are coal wastes, waste piles, disposal sites, and other features which can seriously damage the environment which OSMRE is authorized under the Act to protect (44 FR 15292–3).

In this regulation the OSMRE declined to add the phrase "crushing and screening" to the final definition of "surface coal mining operations" at 30 CFR 700.5, because both the proposed and final definition contained phrases which are readily interpreted to include crushing and screening (44 FR 14914). However, neither the preamble nor the regulations addressing coal preparation plants at 30 CFR Part 827 mention "crushing or screening" and the phrase "and separates coal from its impurities" was retained in the final definition of coal preparation without preamble discussion.

In June 1980, OSMRE proposed to amend the definition of coal processing plants by changing the phrase" . . . *and* separated from its impurities" to ". . . *or* separated from its impurities". This was done to "clarify that chemical or physical processing is included within the scope regardless of whether processing is accomplished by separation of coal from its impurities" (45 FR 42335). However there had been no previous preamble discussions of this definition implying such an interpretation. The proposed rule was never promulgated.

Under proposed revisions in June 1982, OSMRE would regulate . . . coal processing plants and associated coal waste disposal areas so long as they are used "in connection with a coal mining activity" (47 FR 27688). As with the 1979 rules, coal processing plants at the point of ultimate coal use were not regulated since these activities would not be considered to be "in connection with" a coal mine.

Within the 1982 proposed revisions (47 FR 27690), a new definition for coal processing was proposed. The language was similar to the 1979 final rule and included this phrase "and separating coal from its impurities". However, in contrast to the 1980 proposed change, the preamble clarified that this proposed definition did not include coal facilities that do not result in the production of a coal processing waste product. By clarifying that coal processing includes only those activities where coal is separated from its impurities, the definition closely followed the common usage of the term in industry and provided for the regulation of those coal processing activities most likely to be associated with the potential for adverse environmental impacts on the land surface as discussed in the 1979 rule.

On May 5, 1983, OSMRE promulgated a final rule establishing regulations for the control of offsite coal preparation plants and support facilities, 48 FR 20392 (1983). In order to clarify OSMRE's jurisdiction, OSMRE adopted new definitions of "coal preparation or coal processing," "coal preparation plant," and "support facilities" and provided new preamble discussions of those rules. In part, the rules adopted in 1983 included a definition of "coal processing or coal preparation" which required that coal be separated from its impurities. The 1983 definition of "support facilities" included proximity as one factor to be considered in making the determination whether a facility was a support facility.

These definitions were challenged in *In Re: Permanent Surface Mining Regulation Litigation (II)*, Civil Action No. 79–1144 (D.D.C. 1984). In a July 6, 1984, opinion in that case, the District Court for the District of Columbia determined that OSMRE's rule was improperly narrow in contrast to the regulatory scope of the Act. Specifically, the Court held that facilities which in any way leach, chemically process, or physically process coal should be regulated as coal preparation plants even if they do not separate coal from its impurities. The Court also held that the Act did not support the

consideration of proximity in determining whether a facility was a support facility. As a result of this ruling, the definitions of "surface coal mining operations," "coal preparation or coal processing," and "coal preparation plant" were remanded to the Secretary. Although the definition of "support facility" was not remanded, the Court's Memorandum Opinion indicated that it also could not stand.

In order to implement the District Court's Order concerning offsite coal preparation plants, OSMRE adopted an interim final rule, which became effective September 10, 1985 (50 FR 28180, July 10, 1985). The interim final rule revised the definition of "surface coal mining operations" in order to clarify that chemical or physical processing of coal would be regulated whenever they were in connection with coal mining. The revision made clear that OSMRE no longer considers the phrase "chemical or physical processing" to be modified by "in situ."

The rule also removed the definition of "coal processing or coal preparation" and adopted new definitions of "coal preparation" and "coal preparation plants" which include crushing, screening and sizing operations as well as other coal processing. The interim final rule also suspended the definition of "support facilities" and adopted performance standards for coal preparation plants.

At the same time as the interim final rule, OSMRE proposed the same language, in order to allow public comment on the rule (50 FR 28180, July 10, 1985). This notice finalizes the rules proposed on July 10, 1985.

II. Discussion of Comments Received and Rules Adopted

A. Amendment to Definition of "Surface Coal Mining Operations"

The statutory authority for the regulation of offsite coal preparation plants originates from the definition of "surface coal mining operations" in section 701(28)(A) of the Act. That definition reads as follows:

"[S]urface coal mining operations" means—[A] activities conducted on the surface of lands in connection with a surface coal mine or subject to the requirements of section 516 surface operations and surface impacts incident to an underground coal mine, the a products of which enter commerce or the operations of which directly or indirectly affect interstate commerce. Such activities include excavation for the purpose of obtaining coal including such common methods as contour, strip, auger, mountaintop removal, box cut, open pit, and area mining, the uses of explosives and blasting, and in situ distillation or retorting, leaching or other chemical or physical processing, and the cleaning, concentrating, or other processing or preparation, loading of coal for interstate commerce at or near the mine site: *Provided, however,* that such activities do not include the extraction of coal incidental to the extraction of other minerals where coal does not exceed 16⅔ per centum of the tonnage of minerals removed for purposes of commercial use or sale or coal explorations subject to section 512 of this Act; and [B] the areas upon which such activities occur or where such activities disturb the natural land surface. Such areas shall also include any adjacent land the use of which is incidental to any such activities, all lands affected by the construction of new roads or the improvement or use of existing roads to gain access to the site of such activities and for haulage, and excavations, workings, impoundments, dams, ventilation shafts, entryways, refuse banks, dumps, stockpiles, overburden piles, spoil banks, culm banks, tailings, holes or depressions, repair areas, storage areas, processing areas, shipping areas and other areas upon which are sited structures, facilities, or other property or materials on the surface, resulting from or incident to such activities.

OSMRE's 1983 regulatory definition of "surface coal mining operations" at 30 CFR 700.5 tracked its statutory counterpart very closely. However, it differed from the statutory definition because several grammatical and punctuation changes had been made to clarify the statutory language. The regulatory definition also reflects clarified language with regard to extraction of coal form coal refuse piles. A complete discussion of the 1983 rule appears at 48 FR 20392, May 5, 1983.

This final rule revises the first paragraph of the 1983 definition in accordance with the District Court's interpretation of the statutory definition. Specifically, the comma between distillation and retorting will be replaced by an "or" and a semicolon will be placed after the phrase "in situ distillation or retorting." This change will mean that "leaching, chemical or physical processing" will no longer be modified by the phrase "in situ." Thus, these activities will be regulated wherever they occur in connection with coal mining.

The new definition revises paragraph (A) to read as follows:

Surface coal mining operations means—(A) Activities conducted on the surface of lands in connection with a surface coal mine or, subject to the requirements of section 516 of the Act, surface operations and subject to the requirements of section 516 of the Act, surface operations and surface impacts incident to an underground coal mine, the products of which enter commerce or the operations of which directly or indirectly affect interstate commerce. Such activities include excavation for the purpose of obtaining coal, including such common methods as contour, strip, auger, mountaintop removal, box cut, open pit, and area mining; the use of explosives and blasting; in situ distillation or retorting; leaching or other chemical or physical processing; and the cleaning, concentrating, or other processing or preparation of coal. Such activities also include the loading of coal for interstate commerce at or near the mine site. Provided, these activities do not include the extraction of coal incidental to the extraction of other minerals, where coal does not exceed 16⅔ percent of the tonnage of minerals removed for purposes of commercial use or sale, or coal exploration subject to section 512 of the Act; and provided further, that excavation for the purpose of obtaining coal includes extraction of coal from coal refuse piles.

Several commenters requested the Secretary to respond to questions with respect to the changes in this definition. Specifically, many commenters wanted to know whether the definition includes coal crushing, screening and sizing activities which do not separate coal from its impurities. Apparently, some commenters were unsure whether the Secretary considers coal crushing, screening and sizing operations to be surface coal mining operations. Under the definition adopted, "leaching, chemical or physical processing of coal" are surface coal mining operations when they are conducted in connection with a coal mine without regard to whether a waste product is produced. Plainly coal crushing, screening and sizing activities involve the physical processing of coal. Under the definition of "coal preparation" adopted today (see below), facilities in connection with a coal mine which do not separate coal from its impurities but which otherwise engage in physical or chemical processing (i.e.: crushing, screening, and sizing facilities) will be regulated as coal preparation plants.

Several commenters also asked whether the phrase "cleaning, concentrating, or other processing or preparation" includes crushing, screening and sizing activities which do not separate coal from its impurities. Merely changing the size of coal is not

cleaning or concentrating it. Furthermore, since crushing, screening and sizing are physical processing, it would be redundant to treat them as other processing. Nonetheless, these activities when in connection with a coal mine are included in the definition of surface coal mining operations. Several commenters asked whether the Secretary places any other restriction on the regulation of facilities which crush, screen and size coal and do not separate coal from its impurities. Under the rule adopted, these operations will be treated like all other coal preparation plants. Thus, they will be regulated wherever they occur, unless they are operated in connection with the end user of the coal. For a discussion of OSMRE's interpretation of the phrase, "in connection with" a coal mine and "in connection with" an end user see 48 FR 20392, 20393, May 5, 1983.

Some commenters felt that the definition of surface coal mining operations should include an explanation of when "power plant" processing operations were "surface coal mining operations." Treatment of facilities located at the point of coal use was discussed in the preamble to the May 5, 1983 rulemaking (48 FR 20392). That discussion is entirely relevant, and contains the following paragraph:

> OSM does not believe that its jurisdiction extends to facilities which are operated solely in conneciton with the end user of the coal product. A facility will not be deemed to be operated in connection with a mine if it is located at the point of ultimate coal use unless it is also located at the site of the mine. OSM will treat all facilities which handle coal as either "in connection with" a mine or "in connection with" an end user (48 FR 20393, May 5, 1983).

This statement was issued in the context of a regulatory scheme that did not regulate as processing plants, facilities which solely crushed or sized coal. Now that such facilities are considered surface coal mining operations, the 1983 interpretation may be viewed as expansive. In order to allow for a full discussion of this issue, OSMRE intends to commence rulemaking with respect to the phrase "in connection with" in the near future.

Commenters requested clarification of what types of facilities are covered by the definitions discussed in A and B above. For instance, one commenter was unsure whether a coal slurry fuel manufacturing plant would have to be regulated. In such a situation, the regulatory authority would have to evaluate whether the facility processed coal as opposed to producing a different product as an end user of coal. However, OSMRE's future rulemaking on "in connection with" may further clarify this issue.

OSMRE received several comments on the applicability of the definition to loading facilities. The statutory definition restricts OSMRE's regulation of loading facilities to "loading of coal at or near a mine site." OSMRE intends to regulate all loading facilities which are at or near a mine site, and believes it may not regulate loading facilities which are not so located, unless other regulated activities are also conducted such as crushing or sizing which would make the facility a coal preparation plant. One commenter asserted that OSMRE should regulate unloading facilities; OSMRE lacks such jurisdiction, unless such facilities are part of or are resulting from or incidental to a coal processing plant or some other regulated facility.

Some commenters felt that once coal had entered interstate commerce, OSMRE had no jurisdiction over coal preparation plants processing such coal. Under the District Court opinion, the Secretary must regulate coal processing even if it is quite distant from a mine, if it is in conneciton with a mine. The issue of "in connection with" will be explored in further rulemaking as noted above.

Some commenters felt that the proposed definition failed to clearly define "surface coal mining operations" to ensure that leaching, physical processing and chemical processing are within the coverage of the definition whether or not conducted in situ and whether or not they separate coal from its impurities. The Secretary has reexamined the proposed language and believes the punctuation changes clearly delineate that the phrase "in situ" modifies the words "distillation or retorting" *only* and that chemical or physical processing and leaching activities are now clearly identified as a separate category of regulable activities. No further ambiguity is anticipated.

B. Definitions at § 701.5

1. Coal Preparation

This rule will replace the 1983 definition of "coal preparation or coal processing" which was formulated on the basis of OSMRE's previous interpretation of section 701(28)(A) of the Act. In its place, the Department adopts a new definition of the term "coal preparation." Under the new definition "coal preparation" means the chemical or physical processing and the cleaning, concentrating or other processing or preparation of coal. Facilities which do not separate coal from its impurities will be included in this definition.

Several commenters raised questions as to the coverage of the term "coal preparation" and requested that the Secretary clarify whether facilities engaging solely in coal crushing, screening or sizing which do not separate coal from its impurities are included under the definition of "coal preparation." As stated above in response to comments on the "surface coal mining operations" definition, the Secretary will treat coal processing operations which do not separate coal from its impurities as coal preparation, and the facilities involved will be treated as coal preparation plants.

Commenters felt that the proposed definition was too broad, and would reach too many coal processing facilities, including "noncaptive coal processing plants." They also felt that it would be an excessive regulatory burden for OSMRE.

The District Court ruled that OSMRE's definition was too narrow. OSMRE is now regulating those facilities within the reach of the Court's decision. Some commenters felt that the proposed definition should clarify that coal preparation and coal preparation plants associated with the end use of coal should not be regulated. As discussed above, coal preparation plants associated with the ultimate use or consumption of coal, are not in connection with a mine, and are not regulated surface coal mining operations.

2. Coal Preparation Plant

The Department is revising the definition of "coal preparation plant" in order to track the revised definition of coal preparation discussed above.

Several commenters requested that the Secretary clarify that crushing, screening and sizing were conducted at a coal preparation plant. Since these activities fall within the definition of coal preparation, by definition they are conducted at coal preparation plants.

One commenter suggested modifying the opening sentence of this definition by replacing the phrase ". . . facilities associated with coal preparation activities . . .", with the phrase ". . . facilities at the site where coal preparation activities occur. . .". The Secretary accepts this suggestion. It is logical to specify that facilities must be located at the site of coal preparation activities to be considered part of the coal preparation plant. However, not considering such facilities as being part of the preparation plant does not mean they will be unregulated. Usually, facilities "associated with" coal preparation activities are operated in

support thereof. Typically, such facilities will be resulting from or incident to the coal preparation and will be properly regulated as support facilities; but these facilities should not be considered part of the preparation plant itself. Finally, OSMRE wishes to emphasize that this regulatory change is not intended to require preparation plants to be at or near a mine site to be regulated under this rule.

One commenter stated that coal loadouts should not be considered to be coal preparation plants. A loading facility which is not associated with any other coal processing or preparation operation would not be part of a coal preparation plant. However, loading facilities which are operated as part of coal preparation operations would be part of a coal preparation plant, and thus, be regulated under the Act.

3. Support Facilities

In the interim final rule the Secretary suspended the definition of "support facilities" in order to implement the July 6, 1984 Court decision in *In Re: Permanent Surface Mining Regulation Litigation II*, No. 79–1144 (D.D.C. 1984). The Court ruled that the determination of whether a facility was subject to the Act could not include an element of proximity.

OSMRE received numerous comments on the definition of "support facilities." Nearly every commenter felt that OSMRE should adopt a new definition of that term.

The Secretary, based on these comments, has decided not to finalize the proposed removal of the definition of "support facilities" and to propose a revised definition in a new rulemaking. The suspension of the definition of "support facilities" will continue until a new definition is adopted.

C. Amendment to 30 CFR 785.21: Schedule for Permitting Coal Preparation Plants

Section 785.21 establishes the permitting requirements for coal preparation plants. As proposed, and as promulgated in the interim final rule, it requires any person who operates or intends to operate a coal preparation plant outside the permit area for a specific mine, other than those located at the site of ultimate use, to obtain a permit. To obtain a permit, an applicant must submit a permit application which demonstrates that the plant will comply with 30 CFR Part 827 and must describe the construction, operation, maintenance, and planned removal of such facilities.

The coal preparation plants that are subject to OSMRE's regulations under the District Court's July 6, 1984, opinion and by the amendments contained herein will be required to obtain a permit. In the interim final rule, OSMRE recognized that considerable time may be involved in applying for and obtaining a permit. In this rule, OSMRE has amended § 785.21 by finalizing the addition of new paragraphs (d) and (e) to set out a reasonable schedule for the permitting of such facilities.

Section 785.21(d)(1) imposed an obligation to apply for a permit. Under paragraph (d)(1) any person who planned to operate a coal preparation plant after May 10, 1986 which was not subject to the regulations of 30 CFR Chapter VII prior to July 6, 1984, had to apply for a permit no later than November 10, 1985.

New paragraph (d)(2) contains an important exception to the requirements of paragraph (d)(1). It provides that those States with State programs that have statutory or regulatory prohibitions precluding the issuance of permits to facilities covered by paragraph (d)(1) had to notify OSMRE by December 9, 1985 that a program change is necessary. Nine states notified OSMRE that they needed to change their programs. These States each established a timetable, which has been approved by OSMRE, of the action to be taken in order to adopt appropriate measures and undertake permitting actions for all of the coal preparation plants located within their jurisdiction. Operators in those States must apply for permits in accordance with these timetables.

New paragraph (e) of § 785.21 provides that any person operating a coal preparation plant subject to regulation under the July 6, 1984, decision and not subject to prohibition by 30 CFR 761.11 will be allowed to continue to operate without a permit until May 10, 1986. Such persons will be allowed to operate past the May 10, 1986 if (1) they have timely filed a permit application pursuant to paragraph (d)(1) or pursuant to a State imposed schedule specified in paragraph (d)(2); (2) the regulatory authority has yet to issue or deny the permit; and (3) the person complies with the applicable performance standards of § 827.13 of 30 CFR Chapter VII.

Several commenters asserted that the time frame for implementation of permitting in states with legal impediments to regulating coal processing operations was too lax. These commenters contended that the Secretary must set aside any State law that is determined to be inconsistent with and therefore superseded by the Federal Act. It is unnecessary to do so. OSMRE or the State will enforce interim standards until the State issues or denies permanent program permits for coal preparation plants. Thus, untimely action by a State will not unduly delay the protections of the Act. To speed the amendment of state programs where necessary, the Secretary adopted an approach of notifying all states of the possible requirement to amend their programs through the July 10, 1985 **Federal Register** notice rather than the normal notification process of 30 CFR 732.17. This eased notification and allowed the States the first opportunity to review and revise their programs.

For those states where state law remains inconsistent with these regulations, OSMRE will take necessary action to implement these regulations in a timely manner.

D. Permitting and Performance Standards for Support Facilities

One commenter felt that the time frames were far too short for industry to comply with the interim final regulations as they apply to support facilities previously excluded from permitting requirements. Section 701(28)(A) of the Act identifies those activities which handle coal and are considered "surface coal mining operations." The following paragraph, 701(28)(B), identifies many activities or facilities which, while not handling coal, are resultant from or incident to those identified in paragraph (A) above.

Most activities or facilities covered by paragraph (B) should have been permitted under the previous definition of support facilities. OSMRE or the State Regulatory Authority will determine on a case-by-case basis whether particular facilities, not previously regulated, are support facilities and the time frames for obtaining permits.

E. Amendments to Part 827

Part 827 of 30 CFR sets forth the permanent program performance standards for coal preparation plants not within the permit area for a specific mine. Where permanent program standards are not already applicable to the coal preparation plants subject to regulation under the District Court's decision, Part 827 requires interim performance standards until the permanent program permit for such plant is issued. Such a provision is reasonable because the permanent program performance standards are tied to the issuance of a permit. The interim program performance standards are keyed to direct enforcement not based upon the existence of a permit.

A change has been made from the proposed and interim final rules to

clarify when a facility had to be operating to be subject to the preparation plant performance standards. Section 827.13(a) of the proposed and interim final rule was applicable to "[p]ersons operating coal preparation plants not subject to [30 CFR Chapter VII] before July 6, 1984. . . ." From this language, it was not entirely clear whether the performance standards applied to persons operating preparation plants after September 10, 1985 (the effective date of the interim final rule), after July 6, 1984 (the date of the district court decision in *In Re Permanent II, supra*), after August 3, 1977 (the date of SMCRA enactment), or after some other date. In this final rule, OSMRE modified the language of § 827.13(a) to make it clear that for these facilities not subject to the 30 CFR Chapter VII before July 6, 1984, the applicable performance standards apply to all such preparation plants that operated after July 6, 1984. Under the court decision, any person operating a preparation plant after July 6, 1984 was conducting a surface coal mining operation and subject to SMCRA. Notwithstanding that a plant may have ceased operations prior to September 10, 1985, the person operating the facility subsequent to July 6, 1984 must reclaim the site in accordance with the applicable performance standards.

Because 30 CFR Part 827 is cross referenced in all Federal programs, OSMRE will apply these standards to all coal preparation plants in a Federal program states or on Indian lands, operated after July 6, 1984.

OSMRE considered applying the rule retroactively to facilities which ceased operating before July 6, 1984. OSMRE has concluded that doing so would not further public policy in light of the nature both of the Surface Mining Act and its application prior to the District Court decision. *See Linkletter v. Walker*, 381 U.S. 618, 627 (1964). From an environmental standpoint, the question of retroactivity relates solely to the reclamation of non-waste-generating facilities which ceased operating prior to July 6, 1984. Generally, such reclamation would involve the removal of abandoned structures that likely are not currently causing large amounts of pollution.

In considering whether to assert enforcement authority over all facilities which ever crushed, screened, sized, or otherwise handled coal since the enactment of the Act, OSMRE has carefully examined the regulatory history of this issue. Until the District Court's decision in 1984, operators could have believed that OSMRE's jurisdiction over such facilities was unresolved and a matter in dispute. A number of operators challenged OSMRE's jurisdiction in this regard. For example, during the initial regulatory program, the Interior Board of Surface Mining Appeals ruled that OSMRE's regulations could not be applied to coal processing plants not located "at or near" a mine site. The interpretation of the "at or near" language was not clarified until March 1979, when OSMRE first promulgated its permanent program rules. Still, the Board did not apply the interpretation retroactively. *Western Engineering* 1 IBSMA 202, 211n.9; *Thoroughfare Coal Company*, 3 IBSMA 72 (1981); *Drummond Coal Co.*, 2 IBSMA 96 (1980); *Falcon Coal Company*, 2 IBSMA 406 (1980); *Wolverine Coal Company*, 2 IBSMA 325 (1980); *Roberts Brothers Coal Company*, 2 IBSMA 284 (1980).

Under the first set of permanent regulatory program rules in effect from March 1979 until May 1983, the confusion continued to exist. As mentioned earlier, the 1979 preamble contained a statement that the term "surface coal mining operations" was readily interpreted to include crushing and screening and there was no need to expressly include those activities in the definition. However, there were no provisions in the regulations under which only crushing and screening away from the mine site were clearly regulated. For instance, OSMRE's definition of coal processing plant in that same rule required that such plants separate coal from its impurities. A reader could have concluded that crushing or screening operations away from the mine site were not surface coal mining operations because they were not processing.

The only other regulations that logically would have applied to crushers and screeners would have been the rules governing support facilities (30 CFR 785.21, 816.181 and 817.181 (1979)). In the 1979 preamble, in the same sentence that stated that coal processing plants were regulated no matter where located, OSMRE also stated that all facilities incident to a mine would be regulated when *at or near* the site, 44 FR 15095 (1979). Because the support facility rules were applied on a case-by-case basis (45 FR 14915), not all crushers, screeners and sizers would have been regulated. Thus, the 1979 rules did not clearly require the regulation of off-site crushers and screeners.

Recognizing these problems, OSMRE proposed to clarify its rules and amend the definition of coal processing on June 24, 1980 (45 FR 42334) to remove the requirement for separation of waste. However, that proposal was never finalized. Lastly, during the period from May 5, 1983 until July 6, 1984, OSMRE's rules provided expressly that coal handling facilities which did not separate coal form its impurities would not be regulated.

Based upon this regulatory history, OSMRE has concluded that, although it has jurisdiction to cover facilities operating prior to July 6, 1984, it would be inequitable to do so. Prior to the district court decision, operators of such facilities could have reasonably believed that the program did not apply to them during their period of operation and they could have made business decisions in reliance upon those beliefs. In addition, retroactive application of the rule to facilities that ceased operations prior to July 6, 1984, would require regulatory authorities to locate all such facilities, find the persons responsible for the operations of such facilities, and attempt to compel reclamation at those sites. Requiring such efforts in the face of the settled expectation of persons who have concluded their operations is not warranted in this instance.

III. Related Issues: Applications of Prohibitions in Section 522(e)

One commenter questioned how a facility which, in its view, was not subject to SMCRA prior to July 6, 1984, could be required to have had valid existing rights (VER) of section 522 (e) effective August 3, 1977. OSMRE sympathizes with the commenter's concern. Although section 522(e) of SMCRA became effective August 3, 1977, the date of enactment of the Act, those facilities which were affected by the July 6, 1984, court decision became clearly subject to the section 522(e) prohibitions on July 6, 1984. Prior to that date, a person in good faith could have begun and have expected to operate such a facility without complying with the section 522(e) prohibitions or the need to establish VER. Based upon such settled expectations, OSMRE will not apply the prohibitions to such facilities which existed on or before July 6, 1984.

If a person began operating such a facility in a section 552(e) area after July 6, 1984, or intends to operate there in the future, a VER must be established. For those facilities in section 522(e) areas which ceased operating after July 6, 1984, the existence of VER during their period of operation is largely academic. As discussed in the preceding section such sites must be reclaimed. The reclamation obligation would not be affected by whether VER existed.

If OSMRE receives an inappropriate response to a "ten day notice" regarding such a facility operating within a section 522(e) area, OSMRE will issue a Notice of Violation which would provide an abatement period of approximately 30 days. In that time, an operator must obtain necessary waivers, provide documentation to demonstrate valid existing rights, demonstrate that the operation was existing on the date of enactment or cease operations and initiate reclamation of the site. Any determination of "valid existing rights" made by OSMRE will be consistent with the March 22, 1985, District Court ruling in *In Re: Permanent Surface Mining Regulation Litigation (II)*, No. 79–1144 (D.D.C. 1985) and the Notice of Suspension published November 10, 1986 (51 FR 41952, 41954).

A commenter asserted that the thirty day period allowed to obtain the necessary waivers or demonstrate Valid Existing Rights (VER) was unduly short. OSMRE rejects this assertion. Operators have been on notice of the need to have VER since July 6, 1984, the date of the court decision and unquestionably since July 10, 1985, the publication date of the interim final rule. Thus no further delay is warranted.

IV. Procedural Matters

Federal Paperwork Reduction Act

The information collection requirements in § 785.21 have been submitted to the Office of Management and Budget for approval. This final rule contains no information collection requirements that were not covered by the previous approval, however additional respondents will have to collect the information as a result of this rule.

Executive Order 12291

The Department of the Interior (DOI) has examined the final rule according to the criteria of Executive Order 12291 (February 17, 1981) and has determined that it is not a major rule and does not require a regulatory impact analysis. This rule will impose only minor costs to the coal industry since relatively few operations will be affected. Likewise, the impact upon the consumers of coal will be negligible.

Regulatory Flexibility Act

The DOI has also determined, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* that the final rule will not have a significant economic impact on a substantial number of small entities. This rule will impact a relatively small number of coal operators the majority of which would not be small entities.

National Environmental Policy Act

OSMRE has prepared an environmental assessment (EA) of the impacts and the cumulative impacts on the human environment of this rulemaking and related rulemakings under the Act. Based on this EA, OSMRE has made a finding that this rule will not significantly adversely affect the quality of the human environment.

Commenters raised questions as to the requirements of NEPA with regard to deletion of the 'support facilities' definition. These commenters contended that the previous EIS's did not discuss the proposed action.

No definition of support facilities was adopted in 1979. Thus, among the alternatives considered in the 1979 EIS, (OSM–EIS–1) and the supplement thereto, was the option of not defining that term. Since the same facilities will be subject to regulation, regardless of definition, there should be no significant environmental impact from this action. However, an environmental assessment has been prepared, and is available from the OSMRE Administrative Record Room, located at Room 5315A, 1100 L Street NW., Washington, DC.

List of Subjects

30 CFR Part 700

Administrative practice and procedure, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 701

Law enforcement, Surface mining, Underground mining.

30 CFR Part 785

Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 827

Coal, Environmental protection, Surface mining, Underground mining.

Accordingly, 30 CFR Parts 700, 701, 785, and 827 are amended as follows:

Dated: April 7, 1987.

J. Steven Griles,

Assistant Secretary for Land and Minerals Management.

PART 700—GENERAL

1. The authority citation for Part 700 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*

2. Section 700.5 is amended by revising paragraph (a) of the definition of "surface coal mining operations" to read as follows:

§ 700.5 Definitions.

* * * * *

Surface coal mining operations mean—

(a) Activities conducted on the surface of lands in connection with a surface coal mine or, subject to the requirements of Section 516 of the Act, surface operations and surface impacts incident to an underground coal mine, the products of which enter commerce or the operations of which directly or indirectly affect interstate commerce. Such activities include excavation for the purpose of obtaining coal, including such common methods as contour, strip, auger, mountain top removal, box cut, open pit, and area mining; the use of explosives and blasting; in situ distillation or retorting; leaching or other chemical or physical processing; and the cleaning, concentrating, or other processing or preparation of coal. Such activities also include the loading of coal for interstate commerce at or near the mine site. *Provided*, these activities do not include the extraction of coal incidental to the extraction of other minerals, where coal does not exceed 16⅔ percent of the tonnage of minerals removed for purposes of commercial use or sale, or coal exploration subject to Section 512 of the Act; and *Provided further*, that excavation for the purpose of obtaining coal includes extraction of coal from coal refuse piles; and

* * * * *

PART 701—PERMANENT REGULATORY PROGRAM

3. The authority citation for Part 701 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*

4. Section 701.5 is amended by revising the definitions of "coal preparation" and "coal preparation plant" to read as follows:

§ 701.5 Definitions.

* * * * *

Coal preparation means chemical or physical processing and the cleaning, concentrating, or other processing or preparation of coal.

Coal preparation plant means a facility where coal is subjected to chemical or physical processing or cleaning, concentrating, or other processing or preparation. It includes facilities associated with coal preparation activities, including, but not

limited to the following: loading facilities; storage and stockpile facilities; sheds; shops, and other buildings; water-treatment and water-storage facilities; settling basins and impoundments; and coal processing and other waste disposal areas.

* * * * *

PART 785—REQUIREMENTS FOR PERMITS FOR SPECIAL CATEGORIES OF MINING

5. The authority citation for Part 785 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*

6. Section 785.21 is amended by revising paragraphs (d) and (e) to read as follows:

§ 785.21 Coal preparation plants not located within the permit area of a mine.

* * * * *

(d)(1) Except as provided in paragraph (d)(2) of this section, any person who operates a coal preparation plant beyond May 10, 1986, that was not subject to this chapter before July 6, 1984, shall have applied for a permit no later than November 11, 1985.

(2)(i) State programs that have a statutory or regulatory bar precluding issuance of permits to facilities covered by paragraph (d)(1) of this section shall notify OSMRE not later than November 7, 1985, and shall establish a schedule for actions necessary to allow the permitting of such facilities as soon as practicable. Not later than December 9, 1985, this schedule shall be submitted to OSMRE for approval.

(ii) Any person who operates a coal preparation plant that was not subject to this chapter before July 6, 1984, in a state which submits a schedule in accordance with paragraph (d)(2)(i) of this section shall apply for a permit in accordance with the schedule approved by OSMRE.

(e) Notwithstanding § 773.11 of this chapter and except as prohibited by § 761.11 of this chapter, any person operating a coal preparation plant that was not subject to this chapter before July 6, 1984, may continue to operate without a permit until May 10, 1986, and may continue to operate beyond that date if: (1) A permit application has been timely filed under paragraph (d)(1) of this section or under a State imposed schedule specified in paragraph (d)(2) of this section, (2) the regulatory authority has yet to either issue or deny the permit, and (3) the person complies with the applicable performance standards of Section 827.13 of this chapter.

PART 827—PERMANENT PROGRAM PERFORMANCE STANDARDS—COAL PREPARATION PLANTS NOT LOCATED WITHIN THE PERMIT AREA OF A MINE

7. The authority citation for Part 827 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*

8. The introductory language of § 827.12 is revised to read as follows:

§ 827.12 Coal preparation plants: Performance standards.

Except as provided in § 827.13 of this part, the construction, operation, maintenance, modification, reclamation, and removal activities at coal preparation plants shall comply with the following:

* * * * *

9. Section 827.13 is revised to read as follows:

§ 827.13 Coal preparation plants: Interim performance standards.

(a) Persons operating or who have operated coal preparation plants after July 6, 1984, which were not subject to this chapter before July 6, 1984, shall comply with the applicable interim or permanent program performance standards of the State in which such plants are located, as follows:

(1) If located in a State in which either interim or permanent program performance standards apply to such plants, the applicable program standards of the State program shall apply;

(2) If located in a State with a State program which must be amended in order to regulate such plants, the interim program performance standards in Subchapter B of this chapter shall apply; and

(3) If located in a State with a Federal program, all such plants shall be subject to the interim program performance standards in Subchapter B of this chapter.

(b) After a person described in paragraph (a) of this section obtains a permit to operate a coal preparation plant, the performance standards specified in § 827.12 shall be applicable to the operation of that plant instead of those specified in paragraph (a) of this section.

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May 11, 1987

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890

Medical Devices; Clarifications of Effective Dates of Requirement for Premarket Approval for Class III Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86N-0317]

21 CFR Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890

Medical Devices; Clarifications of Effective Dates of Requirement for Premarket Approval for Class III Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is clarifying its device classification regulations by codifying a statement on whether FDA has established an effective date by which manufacturers must submit to FDA applications for premarket approval (PMA's) or notices of completion of product development protocols (PDP's) for certain devices already classified into class III (premarket approval). The rule does not contain any new requirements, but only clarifies the applicable statutory requirements that were described in the preambles to the device classification regulations.

EFFECTIVE DATE: June 10, 1987.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.). Depending upon the levels of regulatory control necessary to assure the safety and effectiveness of devices, under section 513 of the act (21 U.S.C. 360c), FDA classifies devices into one or more of three regulatory categories: class I (general controls), class II (performance standards), or class III (premarket approval).

FDA's classifications of preamendments devices that were promulgated in regulations published in the **Federal Register** before 1986 are in 21 CFR Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890. Although FDA provided sufficient explanations in the preambles to these classification regulations when it promulgated them, the agency did not specify in the codified language for a device being classified into class III the effective date, if any, by which a manufacturer must submit to FDA an application for premaket approval for the device or a notice of completion of a PDP for the device. FDA now is clarifying the regulations by inserting in the codified language information regarding whether FDA has established, for each class III device, an effective date of the requirement for premarket approval for class III devices. In most cases, the agency has not established such a requirement. Further, FDA is correcting certain language inconsistencies in several of the general provisions sections of the classification regulations.

This rule does not contain any new requirements, but merely clarifies the applicable statutory requirements that were described in the preambles to certain proposed and final device classification regulations. Because these amendments do not alter the rights and interests of parties and because, for good cause, FDA finds that public procedures are unnecessary, the rule is exempt from the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 553(b)).

The agency has determined under 21 CFR 25.24(e)(2) 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.

The agency has examined the economic impact of this rule and has determined that it does not require a regulatory impact analysis, as specified in Executive Order 12291, because the rule does not impose any new requirements. Therefore, the agency concludes that the rule is not a major rule as defined in Executive Order 12291. This final rule, published without a proposed rule, is exempt from the Regulatory Flexibility Act (Pub. L. 96-354). The rule does not impose any paperwork requirements.

List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 868

Medical devices.

21 CFR Part 870

Medical devices.

21 CFR Part 876

Medical devices.

21 CFR Part 880

Medical devices.

21 CFR Part 882

Medical devices.

21 CFR Part 884

Medical devices.

21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citations under the sections in 21 CFR Part 864 are removed and the authority citation for 21 CFR Part 864 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 552-559, 565-574, 576-577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Section 864.1 is revised to read as follows:

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

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

3. By adding new § 864.3 to subpart A to read as follows:

§ 864.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under

section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

4. Section 864.5220 is amended by adding new paragraph (c) to read as follows:

§ 864.5220 Automated differential cell counter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

5. Section 864.5680 is amended by adding new paragraph (c) to read as follows:

§ 864.5680 Automated heparin analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

6. Section 864.7250 is amended by adding new paragraph (c) to read as follows:

§ 864.7250 Erythropoietin assay.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

7. Section 864.7300 is amended by adding new paragraph (c) to read as follows:

§ 864.7300 Fibrin monomer paracoagulation test.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

8. Section 864.9205 is amended by adding new paragraph (c) to read as follows:

§ 864.9205 Blood and plasma warming device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 864.3.

9. Section 864.9245 is amended by adding new paragraph (c) to read as follows:

§ 864.9245 Automated blood cell separator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

10. The authority citations under the sections in 21 CFR Part 866 are removed and the authority citation for 21 CFR Part 866 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

11. By revising § 866.1 to read as follows:

§ 866.1 Scope.

(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.

(b) The indentification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an immunology and microbiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a microbiology device) is listed only in one subpart.

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

12. By adding new § 866.3 to Subpart A to read as follows:

§ 866.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (Premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of

the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been sutstantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

13. Section 866.2420 is amended by adding new paragraph (c) to read as follows:

§ 866.2420 Oxidase screening test for gonorrhea.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 866.3.

14. Section 866.3290 is amended by adding new paragraph (c) to read as follows:

§ 866.3290 Gonococcal antibody test (GAT).

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 866.3.

15. Section 866.3305 is amended by adding new paragraph (c) to read as follows:

§ 866.3305 Herpes simplex virus serological reagents.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 866.3.

16. Section 866.3510 is amended by adding new paragraph (c) to read as follows:

§ 866.3510 Rubella virus serological reagents.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 866.3.

17. Section 866.6010 is amended by adding new paragraph (c) to read as follows:

§ 866.6010 Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 866.3.

PART 868—ANESTHESIOLOGY DEVICES

18. The authority citations under the sections in 21 CFR Part 868 are removed and the authority citation for 21 CFR Part 868 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

19. By revising § 868.1 to read as follows:

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

20. By adding new § 868.3 to subpart A to read as follows:

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order

approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

21. Section 868.1120 is amended by adding new paragraph (c) to read as follows:

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 866.3.

22. Section 868.1150 is amended by adding new paragraph (c) to read as follows:

§ 868.1150 Indwelling blood carbon dioxide partial pressure ($P_{CO}2$) analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

23. Section 868.1170 is amended by adding new paragraph (c) to read as follows:

§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

24. Section 868.1200 is amended by adding new paragraph (c) to read as follows:

§ 868.1200 Indwelling blood oxygen partial pressure (P_O2) analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

25. Section 868.2450 is amended by adding new paragraph (c) to read as follows:

§ 868.2450 Lung water monitor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

26. Section 868.2500 is amended by adding new paragraph (c) to read as follows:

§ 868.2500 Cutaneous oxygen monitor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 868.3.

27. Section 868.5400 is amended by adding new paragraph (c) to read as follows:

§ 868.5400 Electroanesthesia apparatus.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

28. Section 868.5610 is amended by adding new paragraph (c) to read as follows:

§ 868.5610 Membrane lung for long-term pulmonary support.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

PART 870—CARDIOVASCULAR DEVICES

29. The authority citations under the sections in 21 CFR Part 870 are removed and the authority citation for 21 CFR part 870 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

30. By revising § 870.1 to read as follows:

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

31. By adding new § 870.3 to subpart A to read as follows:

§ 870.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order

approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

32. Section 870.1025 is amended by adding new paragraph (c) to read as follows:

§ 870.1025 Arrhythmia detector and alarm.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

33. Section 870.1350 is amended by adding new paragraph (c) to read as follows:

§ 870.1350 Catheter balloon repair kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

34. Section 870.1360 is amended by adding new paragraph (c) to read as follows:

§ 870.1360 Trace microsphere.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

35. Section 870.3300 is amended by adding new paragraph (c) to read as follows:

§ 870.3300 Arterial embolization device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

36. Section 870.3375 is amended by adding new paragraph (c) to read as follows:

§ 870.3375 Cardiovascular intravascular filter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

37. Section 870.3450 is amended by adding new paragraph (c) to read as follows:

§ 870.3450 Vascular graft prosthesis of less than 6 millimeters diameter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

38. Section 870.3535 is amended by adding new paragraph (c) to read as follows:

§ 870.3535 Intra-aortic balloon and control system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

39. Section 870.3545 is amended by adding new paragraph (c) to read as follows:

§ 870.3545 Ventricular bypass (assist) device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

40. Section 870.3600 is amended by adding new paragraph (c) to read as follows:

§ 870.3600 External pacemaker pulse generator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

41. Section 870.3610 is amended by adding new paragraph (c) to read as follows:

§ 870.3610 Implantable pacemaker pulse generator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

42. Section 870.3620 is amended by adding new paragraph (c) to read as follows:

§ 870.3620 Pacemaker lead adaptor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

43. Section 870.3680 is amended by adding new paragraph (c) to read as follows:

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

44. Section 870.3700 is amended by adding new paragraph (c) to read as follows:

§ 870.3700 Pacemaker programmers.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

45. Section 870.3710 is amended by adding new paragraph (c) to read as follows:

§ 870.3710 Pacemaker repair or replacement material.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

46. Section 870.3800 is amended by adding new paragraph (c) to read as follows:

§ 870.3800 Annuloplasty ring.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

47. Section 870.3850 is amended by adding new paragraph (c) to read as follows:

§ 870.3850 Carotid sinus nerve stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

48. Section 870.3925 is amended by adding new paragraph (c) to read as follows:

§ 870.3925 Replacement heart valve.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

49. Section 870.4230 is amended by adding new paragraph (c) to read as follows:

§ 870.4230 Cardiopulmonary bypass defoamer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

50. Section 870.4260 is amended by adding new paragraph (c) to read as follows:

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

51. Section 870.4320 is amended by adding new paragraph (c) to read as follows:

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

52. Section 870.4350 is amended by adding new paragraph (c) to read as follows:

§ 870.4350 Cardiopulmonary bypass oxygenator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

53. Section 870.4360 is amended by adding new paragraph (c) to read as follows:

§ 870.4360 Nonroller-type cardiopulmonary bypass blood pump.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

54. Section 870.5200 is amended by adding new paragraph (c) to read as follows:

§ 870.5200 External cardiac compressor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

55. Section 870.5225 is amended by adding new paragraph (c) to read as follows:

§ 870.5225 External counter-pulsating device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

56. Section 870.5300 is amended by adding new paragraph (c) to read as follows:

§ 870.5300 DC-defibrillator (including paddles).

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

57. Section 870.5550 is amended by adding new paragraph (c) to read as follows:

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

58. The authority citations under the sections in 21 CFR Part 876 are removed and the authority citation for Part 876 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

59. By revising § 876.1 to read as follows:

§ 876.1 Scope.

(a) This part sets forth the classification of gastroenterology-urology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a gastroenterology-urology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

60. By adding new § 876.3 to Subpart A to read as follows:

§ 876.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commerically distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into

commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

61. Section 876.3350 is amended by adding new paragraph (c) to read as follows:

§ 876.3350 Penile inflatable implant.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

62. Section 876.3630 is amended by adding new paragraph (c) to read as follows:

§ 876.3630 Penile rigidity implant.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

63. Section 876.3750 is amended by adding new paragraph (c) to read as follows:

§ 876.3750 Testicular prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

64. Section 876.4480 is amended by adding new paragraph (c) to read as follows:

§ 876.4480 Electrohydraulic lithotriptor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

65. Section 876.5220 is amended by adding new paragraph (c) to read as follows:

§ 876.5220 Colonic irrigation system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device intended for the uses described in paragraph (b)(2). See § 876.3.

66. Section 876.5270 is amended by adding new paragraph (c) to read as follows:

§ 876.5270 Implanted electrical urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

67. Section 876.5280 is amended by adding new paragraph (c) to read as follows:

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

68. Section 876.5540 is amended by adding new paragraph (c) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 876.3.

69. Section 876.5860 is amended by adding new paragraph (c) to read as follows:

§ 876.5860 High permeability hemodialysis system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

70. Section 876.5870 is amended by adding new paragraph (c) to read as follows:

§ 876.5870 Sorbent hemoperfusion system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

71. Section 876.5955 is amended by adding new paragraph (c) to read as follows:

§ 876.5955 Peritoneo-venous shunt.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 876.3.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

72. The authority citations under the sections in 21 CFR Part 880 are removed and the authority citation for Part 880 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

73. By revising § 880.1 to read as follows:

§ 880.1 Scope.

(a) This part sets forth the classification of general hospital and personal use devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a general hospital and personal use device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

74. By adding new § 880.3 to Subpart A to read as follows:

§ 880.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring

completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" devices defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

75. Section 880.5130 is amended by adding new paragraph (c) to read as follows:

§ 880.5130 Infant radiant warmer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 880.3.

76. Section 880.5760 is amended by adding new paragraph (c) to read as follows:

§ 880.5760 Chemical coldpack snakebite kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 880.3.

PART 882—NEUROLOGICAL DEVICES

77. The authority citations under 21 CFR Part 882 are removed and the authority citation for 21 CFR Part 882 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

78. By revising § 882.1 to read as follows:

§ 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

79. By adding new § 882.3 to subpart A to read as follows:

§ 882.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

80. Section 882.1790 is amended by adding new paragraph (c) to read as follows:

§ 882.1790 Ocular plethysmograph.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No efective date

has been established of the requirement for premarket approval. See § 882.3.

81. Section 882.1825 is amended by adding new paragraph (c) to read as follows:

§ 882.1825 Rheoencephalograph.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

82. Section 882.5150 is amended by adding new paragraph (c) to read as follows:

§ 882.5150 Intravascular occluding catheter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirements for premarket approval. See § 882.3.

83. Section 882.5800 is amended by adding new paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirements for premarket approval. See § 882.3.

84. Section 882.5840 is amended by adding new paragraph (c) to read as follows:

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirements for premarket approval. See § 882.3.

85. Section 882.5850 is amended by adding new paragraph (c) to read as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

86. Section 882.5860 is amended by adding new paragraph (c) to read as follows:

§ 882.5860 Implanted neuromuscular stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirements for premarket approval. See § 882.3.

87. Section 882.5940 is amended by adding new paragraph (c) to read as follows:

§ 882.5940 Electroconvulsive therapy device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirements for premarket approval. See § 882.3.

88. Section 882.5950 is amended by adding new paragraph (c) to read as follows:

§ 882.5950 Artificial embolization device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

89. The authority citations under the sections in 21 CFR Part 884 are removed and the authority citation for Part 884 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

90. By revising § 884.1 to read as follows:

§ 884.1 Scope.

(a) This part sets forth the classification of obstetrical and gynecological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a obstetrical and gynecological device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

91. By adding new § 884.3 to Subpart A to read as follows:

§ 884.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device

states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

92. Section 884.1060 is amended by adding new paragraph (c) to read as follows:

§ 884.1060 Endometrial aspirator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

93. Section 884.1100 is amended by adding new paragraph (c) to read as follows:

§ 884.1100 Endometrial brush.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

94. Section 884.1185 is amended by adding new paragraph (c) to read as follows:

§ 884.1185 Endometrial washer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

95. Section 884.2050 is amended by adding new paragraph (c) to read as follows:

§ 884.2050 Obstetric data analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

96. Section 884.2620 is amended by adding new paragraph (c) to read as follows:

§ 884.2620 Fetal electroencephalographic monitor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

97. Section 884.2685 is amended by adding new paragraph (c) to read as follows:

§ 884.2685 Fetal scalp clip electrode and applicator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

98. Section 884.4100 is amended by adding new paragraph (c) to read as follows:

§ 884.4100 Endoscopic electrocautery and accessories.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

99. Section 884.4150 is amended by adding new paragraph (c) to read as follows:

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

100. Section 884.4250 is amended by adding new paragraph (c) to read as follows:

§ 884.4250 Expandable cervical dilator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

101. Section 884.4270 is amended by adding new paragraph (c) to read as follows:

§ 884.4270 Vibratory cervical dilators.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

102. Section 884.5050 is amended by adding new paragraph (c) to read as follows:

§ 884.5050 Metreurynter-balloon abortion system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

103. Section 884.5225 is amended by adding new paragraph (c) to read as follows:

§ 884.5225 Abdominal decompression chamber.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

104. Section 884.5380 is amended by adding new paragraph (c) to read as follows:

§ 884.5380 Contraceptive tubal occlusion device (TOD) and introducer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

105. Section 884.5940 is amended by adding new paragraph (c) to read as follows:

§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

PART 890—PHYSICAL MEDICINE DEVICES

106. The authority citations under the sections in 21 CFR Part 890 are removed and the authority citation for 21 CFR Part 890 is revised to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

107. By revising § 890.1 to read as follows:

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine device intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

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

108. By adding new § 890.3 to Subpart A to read as follows:

§ 890.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under

section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application of premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, includiing a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commerically distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

109. Section 890.3610 is amended by adding new paragraph (c) to read as follows:

§ 890.3610 Rigid pneumatic structure orthosis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 890.3.

110. Section 890.3890 is amended by adding new paragraph (c) to read as follows:

§ 890.3890 Stair-climbing wheelchair.

* * * * *

(c) *Date PMA or notice or completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 890.3.

111. Section 890.5275 is amended by adding new paragraph (c) to read as follows:

§ 890.5275 Microwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragrah (b)(1). See § 890.3.

112. Section 890.5290 is amended by adding new paragraph (c) to read as follows:

§ 890.5290 Shortwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

113. Section 890.5300 is amended by adding new paragraph (c) to read as follows:

§ 890.5300 Ultrasonic diathermy.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

114. Section 890.5525 is amended by adding new paragraph (c) to read as follows:

§ 890.5525 Iontophoresis device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

115. Section 890.5860 is amended by adding new paragraph (c) to read as follows:

§ 890.5860 Ultrasound and muscle stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* No effecttive date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

Dated: April 17, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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