circumstances where, due to the nature of the research being supported, the Foundation requires greater control over resulting inventions. The NSF Grants or Contracts Officer, with concurrence of the cognizant Program Manager, will negotiate a background rights provision. If the affected awardee is a small business firm or nonprofit organization, the provision will conform to the requirements of the Bayh-Dole Act (35 U.S.C. 202(f)) as implemented by 37 CFR 401.12).

§ 650.17 Subcontracts.

As provided in paragraph (g) of the Patent Rights clause in § 650.4(a), awardees should normally use that clause in all subcontracts. At the request of the awardee or subcontractor or on recommendation from NSF staff, the cognizant Grants or Contracts Officer may direct the awardee to insert into subcontracts relating to scientific research a special patent provision negotiated under § 650.5.

§ 650.18 Delegation of Authority.

The General Counsel is responsible for implementing this regulation and is authorized to make any exceptions to or extensions of the NSF Patent Policy as may be required by particular circumstances. The General Counsel will designate the NSF Patent Assistant and that individual is authorized to carry out the functions assigned by this regulation.

Appendix A to Part 650—Optional Format for Confirmatory License

The following format may be used for the confirmatory license to the Government required by subparagraph (f)(5) of the Patent Rights clause in § 650.4(a). Any equivalent instrument may also be used.

License to the United States Government

This instrument confirms to the United States Government, as represented by the National Science Foundation, an irrevocable, nonexclusive, nontransferable, royalty-free license to practice or have practiced on its behalf throughout the world the following subject invention:

(invention title)

(inventor[s] name[s])

(patent application number and filing date)

(country, if other than United States)

(NSF Disclosure No.).

This subject invention was made with NSF support through:

(grant or contract number)

(grantee or contractor).

Principal rights to this subject invention have been left with the licensor.

Signed: _____

Name: _____

Title: _____

Date: _____

Accepted on behalf of the Government:

_____

NSF Patent Assistant

Date: _____

[FR Doc. 92-9640 Filed 4-27-92; 8:45 am]

BILLING CODE 7555-01-M

federal register

Tuesday
April 28, 1992

Part V

Department of the Interior

Bureau of Indian Affairs

Fiscal Year 1992–1994 Plan for Services to Indian Children With Disabilities and Their Families; Notice of Public Hearings

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Fiscal Year 1992–1994 Plan for Services to Indian Children With Disabilities and Their Families

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of public hearings.

SUMMARY: Notice is hereby given that the Office of Indian Education Programs (OIEP), Branch of Exceptional Education, has completed the required application "State Plan" for funds under Part B of the Individuals with Disabilities Education Act, Public Law 101–476. The application describes activities that will provide education and related services for Indian Children with Disabilities (ages 5–21) served by elementary and secondary schools funded by the Bureau of Indian Affairs, Department of the Interior.

The application is available to all interested parties and members of the general public. Each BIA Area/Agency Education will have copies of the application available for inspection. In addition, copies may be obtained from the Branch of Exceptional Education by calling (202) 208–6675.

Public hearings will be held at some school locations. Persons interested in making public comment should contact the local BIA Area/Agency Education Offices listed below for more information. Individuals who make public comment are encouraged to submit a written statement summarizing their comments to the proctor at the actual hearing.

DATES: Written comments must be received at the address listed below no later than May 10, 1992:

ADDRESSES: Office of Indian Education Programs, Branch of Exceptional Education, Attn: Marie J. Emery, MS 3530 MIB Code 523, 1849 C Street, NW., Washington, DC 20240–4000.

FOR FURTHER INFORMATION CONTACT: Goodwin K. Cobb, III at the above address or call (202) 208–6675, FAX (202) 208–5993. Office of Indian Education Programs, Branch of Exceptional Education, MS 3530 MIB Code 523, 1849 C Street NW., Washington, DC 20240–4000.

Dated: April 17, 1992.

William D. Bettenberg,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 92–9712 Filed 4–27–92; 8:45 am]

BILLING CODE 4310–02–M

Federal Register

Tuesday
April 28, 1992

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 807

Medical Devices; Substantial Equivalence; 510(k) Summaries and Statements; Class III Summaries; Confidentiality of Information; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 807

[Docket No. 91N-0388]

Medical Devices; Substantial Equivalence; 510(k) Summaries and 510(k) Statements; Class III Summaries; Confidentiality of Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to implement provisions of the Safe Medical Devices Act of 1990 (SMDA) which require persons who submit a premarket notification to provide to FDA, as part of the submission, an adequate summary of any information respecting safety and effectiveness or a statement that such information will be made available upon request by any person. The interim rule prescribes the content and format of these submissions. The interim rule also implements the requirement that 510(k) submitters, claiming substantial equivalence to a class III preamendments device for which FDA has not yet called for premarket approval, submit a class III summary and certify that they have conducted a search of safety and effectiveness data. In addition, the interim rule amends the medical device regulations governing the confidentiality of certain premarket notification submissions and their summaries to conform to the SMDA. FDA is also requiring that persons who submit a premarket notification (510(k)) certify that the data and information are truthful and accurate and that no material fact has been omitted.

DATES: Written comments by June 29, 1992. This interim rule will become effective May 28, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1190.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority and Legislative History

On May 28, 1976, Congress enacted the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) to expand FDA's authority to regulate the introduction of medical devices into interstate commerce and thereby ensure their safety and effectiveness. Section 510(k) of the act (21 U.S.C. 360(k)) authorizes FDA to issue regulations to require persons who propose to begin commercial distribution of a device intended for human use into interstate commerce to report to FDA the class in which the device is classified under section 513 of the act (21 U.S.C. 360c) or, if such person determines that the device is not classified under such section, a statement of that determination and the basis for the determination that the device is or is not so classified. This premarket notification must be furnished to FDA at least 90 days before introduction of the device into commercial distribution. On August 23, 1977, FDA issued final regulations establishing the requirements for the form and manner in which premarket notifications (510(k) submissions) are to be sent to FDA. These regulations also contained provisions governing public disclosure by FDA of the existence of a 510(k) submission.

On November 28, 1990, the President signed into law the SMDA (Pub. L. 101-629) which amended the act. The SMDA requires that a premarket notification under section 510(k) include an adequate summary of any information on safety and effectiveness (510(k) summary) or a statement (510(k) statement) that such information will be made available upon request by any person. Section 12(a) of the SMDA added section 513(i)(3)(B) of the act (21 U.S.C. 360c(i)(3)(B)), which requires FDA to make available to the public any 510(k) summary within 30 days of the issuance of a determination of substantial equivalence. Section 12(b) of the SMDA directs the Secretary to issue regulations establishing the requirements of the summaries under section 513(i)(3)(B) of the act.

The SMDA also requires that persons who submit a premarket notification (submitters) claiming substantial equivalence to a class III device introduced into interstate commerce before December 1, 1990, and for which FDA has not required premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)), certify that they have conducted a reasonable search of all information known or otherwise available to them about the class III device and other similar legally marketed devices (class III certification.) Submitters are also required under section 513(f)(3) of the act to submit a summary (class III summary) of, and a citation to, all adverse safety and effectiveness data associated with the devices being compared. FDA may require the submitter to submit the safety and effectiveness data described in the class III summary.

B. Section 510(k) Summaries

The regulation prescribes the content and format of the summary of safety and effectiveness information required to be submitted under section 513(i)(3) of the act (510(k) summaries). The regulation defines a 510(k) summary as a summary of the safety and effectiveness information contained in the premarket notification submission upon which a determination of substantial equivalence can be based. This safety and effectiveness information includes data supporting a finding of substantial equivalence and all adverse safety and effectiveness data and information on the device. The decision to submit either a 510(k) summary or a 510(k) statement may not be changed once the premarket notification submission has been received by FDA. FDA's decision regarding the existence of substantial equivalence will be based on all the information contained in the 510(k), not only the information contained in the summary. Indeed, FDA may not review all 510(k) summaries due to resource constraints. Submitters are nevertheless required to prepare an adequate summary.

FDA believes that the intent of the requirement that premarket notification submitters provide either a 510(k) summary or a 510(k) statement is to make available to the public information about a device for which a marketing order has been issued and to provide the public with insight into the basis for an equivalence determination. FDA will make publicly available on a regular basis a list of all premarket notification submissions for which substantial equivalence determinations have been made, and information as to whether a 510(k) summary or a 510(k) statement was included. Summaries will be available to the public in accordance with the requirements of section 12(a) of the SMDA. Because 510(k) summaries submitted in premarket notifications are intended, in part, for public disclosure, they are not subject to predisclosure

notification under Executive Order 12600.

The content requirements for 510(k) summaries in this regulation describe the information FDA relies on in determining substantial equivalence. A detailed discussion of FDA's decisionmaking process is contained in FDA's Guidance on the Premarket Notification Review Program. This publication is available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 800–638–2041 or 301–443–6597. Premarket notification submissions must contain adequate information to permit FDA to conclude whether the new device has the same intended use and technological characteristics as the predicate device. If the device has different technological characteristics, the information in the premarket notification submission must demonstrate that the device is as safe and effective as the predicate device and does not raise any new questions concerning safety and effectiveness. The term different technological characteristics means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the predicate device.

Because the content requirements for a 510(k) summary are different depending on the type of supporting data required in a premarket notification submission, it is important to understand the different types of data that may be submitted. All submissions must contain descriptive data and information sufficient to describe clearly the intended use, physical composition, method of operation, specifications, and performance claims of the new device. Any similar information submitted with respect to the predicate or legally marketed device is also considered descriptive data.

Under certain circumstances, FDA requires performance testing information, i.e., data from bench, animal, or clinical tests, to support an assertion that the device performs according to its description. Generally, FDA will not require performance testing data to support substantial equivalence if there are no significant differences in the technological characteristics of the new device and the predicate or legally marketed device, i.e., the new device involves no new materials, methods of operation, etc., and its descriptive characteristics and precise enough to ensure that the devices will perform comparably if the new device is manufactured according to its description.

In contrast, FDA generally will require performance testing data to establish substantial equivalence if a new device has different technological characteristics than a predicate or legally marketed device, or when the descriptive characteristics of the devices are insufficient to ensure that the devices will perform comparably. In these cases, performance testing data are necessary to demonstrate that the new characteristics of the device do not cause it to perform less safely or less effectively than the legally marketed device to which it is being compared.

The regulations delineating the contents of a 510(k) summary are designed to be sufficiently flexible to permit the summary to be as simple or as complex as the supporting information that it is summarizing. In accordance with § 807.92(a), summaries of premarket notification submissions containing only descriptive information to support equivalence would be required to contain only general information about the device and a summary of the descriptive information respecting safety and effectiveness supporting equivalence. FDA believes that these 510(k) summaries should be brief, generally not exceeding one page.

In contrast, when the determination of substantial equivalence is based on an assessment of performance data, the supporting information is generally more voluminous and more complex. Accordingly, § 807.92(a) and (b) require that the 510(k) summaries for these submissions be more comprehensive, and contain descriptions and analyses of the performance data included in the premarket notification submissions. As a result, FDA expects the 510(k) summaries for these submissions to be lengthier than for submissions containing descriptive information only. FDA reminds 510(k) summary preparers that the 510(k) summary is not intended to be a reproduction of the premarket notification. Rather, it should be a clear and concise discussion of the information respecting safety and effectiveness contained in the submission that supports a determination of substantial equivalence.

In determining whether the new device has the same intended use as a predicate device, FDA assesses any differences in indications for use in terms of the safety and effectiveness questions they may raise. The labeling for a new device need not contain the identical therapeutic or diagnostic statements that appear in the labeling of a predicate device in order for FDA to conclude that the devices have the same intended use. FDA may determine that a new device is substantially equivalent to a predicate device even though the indications may differ in certain respects, provided that these differences do not pose new questions concerning safety or effectiveness that were not posed by the intended use of the predicate device. Ordinarily, FDA relies on descriptive information alone in deciding whether any differences in indications preclude a finding of substantial equivalence. However, where the equivalence determination is based on information obtained from limited testing, the summary should include that information, as required in § 807.92(b).

C. Section 510(k) Statements

In accordance with section 513(i)(1)(B)(3)(A) of the act (21 U.S.C. 360c(i)(B)(3)(A)), in lieu of submitting a 510(k) summary, premarket notification submitters may provide the agency with a 510(k) statement that the submitter will make available information in the premarket notification on safety and effectiveness upon request by any person. The information to be made available includes adverse safety and effectiveness information in the premarket notification submission that supports a finding of substantial equivalence. FDA believes that confidential information concerning patient identifiers, however, would not be required to be disclosed. FDA is adding new § 807.93 to describe the contents of a 510(k) statement.

While the regulations do not contain specific requirements as to how firms should release safety and effectiveness information to requestors, FDA believes that such requests should be filled within 30 days of their receipt. FDA believes that, in most cases, the requirement to provide an adequate summary of information on safety and effectiveness would be satisfied by making available those parts of the premarket notification submission relating to the finding of equivalence, descriptive information, and performance testing results, including detailed information concerning adverse health effects. Because a determination of substantial equivalence is based only on the information contained in a premarket notification, and because the submitter is required to include in its submission all pertinent data in support of its claim of equivalence, FDA believes that the information a submitter is required to furnish in response to a request for information should be taken

only from the information contained in the premarket notification submission. In the case of a dispute over the adequacy of the information released to a requestor by a premarket notification submitter, FDA believes that the entire premarket notification, excluding confidential patient identifiers and other confidential information that is not safety and effectiveness information, should be released. Failure to comply with the commitment made in a 510(k) statement is a prohibited act under section 301(q)(2) of the act (21 U.S.C. 331(q)(2)).

Where a premarket notification submitter elects to provide a statement rather than a summary, the interim rule does not provide for exclusion of trade secret or confidential commercial information that is also considered safety and effectiveness information from the information disclosed by the submitter to any person who requests the information. Earlier informal statements made by FDA officials about section 513(i)(1)(B)(3)(A) of the act contemplated that confidential safety and effectiveness information could be excluded from the information given to requesters. In developing this interim rule, however, FDA found that this position was unsupported by the statute and legislative history. FDA expects that sponsors that do not wish to disclose safety and effectiveness information they regard as confidential are likely to elect to submit summaries instead of 510(k) statements. FDA specifically requests comments on this issue.

II. Class III Summaries and Class III Certification

In accordance with section 4 of the SMDA (21 U.S.C. 360c(f)(3)), new § 807.87(i) is being added to require submitters of premarket notification submissions claiming substantial equivalence to a class III device for which no final regulation requiring premarket approval applications has been issued under section 515(b) of the act to include a summary of and a citation to all adverse safety and effectiveness data on the device and its predicate (class III summary). The section requires the submitter to certify that a reasonable search of all information known or otherwise available on the predicate device has been conducted (class III certification).

A. Summaries

FDA has interpreted the adverse safety and effectiveness data referred to in this section to include the types of safety and effectiveness problems to which that type of class III predicate device is suspectible and the potential causes of such problems. The summary of adverse safety and effectiveness data required for these submissions should be based upon a reasonable search of all information known or otherwise available to the 510(k) submitter about the type of class III predicate or legally marketed device to which the device that is the subject of the premarket notification submission is being compared. FDA does not believe that preparation of such a summary should necessitate original research or speculative forecasting by a 510(k) submitter. Limiting the class III summary and class III certification to adverse safety and effectiveness information known only about the device for which the premarket notification was submitted and a single predicate or legally marketed device is not consistent with Congressional intent of ensuring that potential adverse safety and effectiveness concerns of that type of device are adequately addressed in a premarket notification. This concern particularly applies in situations where there is limited clinical experience with the subject device. FDA is establishing a format for the class III certification in § 807.94.

B. Truthfulness and Accuracy Certification

As a result of an Office of the Inspector General's July 1990 report on internal control of the 510(k) process, FDA is adding new § 807.87(j), requiring persons who submit a premarket notification to certify the truthfulness and accuracy of the submission.

III. Confidentiality of Premarket Notification Submissions

The agency recognizes that the intent to market a device is often considered confidential commercial information because premature disclosure of a firm's marketing plans could provide a competitive advantage to the firm's competitors. This economic reality is reflected in § 807.95(b), which establishes a procedure whereby a submitter may request that FDA hold as confidential a premarket notification submission for a device that is not on the market and for which the intent to market has not been disclosed. In accordance with that section, FDA will treat a premarket notification as confidential if the submitter certifies in writing:

(1) That the submitter considers the intent to market the device to be confidential commercial information,

(2) That neither the submitter nor anyone else has disclosed the intent to market the device to certain enumerated individuals,

(3) That the person will notify the agency if the intent to market the device is disclosed to certain enumerated individuals,

(4) That the submitter has taken precautions to protect the confidentiality of its intention to market a device, and

(5) That the submitter understands that the submission to the government of false information is prohibited, and if FDA agrees that the intent to market the device is confidential commercial information.

FDA believes that § 807.95(b) is affected by the enactment of section 513(i) of the act. As stated above, the summary disclosure requirement in section 513(i)(3)(B) of the act becomes effective only when the agency has issued a determination of substantial equivalence. Therefore, a submitter may continue to request confidentiality in accordance with § 807.95(b), so long as the agency has not yet issued a determination that the device is substantially equivalent to another device.

Section 807.95(c) prescribes the length of time that the agency will protect the confidentiality of a submitter's intent to market a device. In general, when the agency determines that the submitter has complied with the procedures described in § 807.95(b), the agency will protect the confidentiality of the intent to market a device for 90 days from the date of FDA's receipt of the premarket notification submission.

Section 807.95(c) provides three situations in which the period of confidential treatment may be extended for more than 90 days. First, § 807.95(c)(1) allows for an extended period of confidentiality when the agency requests additional information regarding the device. Because it applies to a situation in which a substantial equivalence determination has not yet been made, § 807.95(c)(1) is unaffected by new section 513(i)(3)(B) of the act.

Second, § 807.95(c)(2) allows the agency to hold a premarket notification submission confidential when a decision has been made that the device cannot be marketed without premarket approval or reclassification. In this situation, the agency has, in effect, made a determination that the manufacturer's device is not substantially equivalent to another device. Consequently, the agency believes that this section is consistent with the new amendments and is unaffected by the enactment of section 513(i)(3)(B) of the act.

The third situation, § 807.95(c)(3), requires modification, however. Section 807.95(e)(3) currently allows the submitter to request that the intent to

market a device be held in confidence for more than 90 days when the submitter has reason to believe that the actual marketing of the device may be delayed and the intent to market has not been disclosed by the submitter. Thus, § 807.95(c)(3) would permit extended confidentiality for a premarket notification submission even after FDA has made a determination that the device is substantially equivalent and, consequently, directly conflicts with new section 513(i)(3)(B) of the act. Therefore, the agency has deleted § 807.95(c)(3) and replaced it with a new provision reflecting the summary disclosure requirements mandated by section 513(i)(3)(B) of the act.

The agency has determined that this rule is a rule of "agency organization, procedure, or practice" and, as such, it is exempt from notice and comment under the Administrative Procedure Act (5 U.S.C. 553(a)(2) and (b)(A)). The Commissioner also finds good cause under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e) to forgo notice and comment as it would be unnecessary and contrary to the public interest to delay implementation of this rule, in as much as it merely implements the plain directives of the statute. As provided in FDA's administrative practices and procedures regulation (21 CFR 10.40(e)), FDA is providing an opportunity for public comment on whether the regulation should be modified or revoked.

IV. Environmental Impact

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.

V. Economic Impact

FDA has carefully examined the economic impact of the rule in accordance with the economic requirements of Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The agency concludes that the rule is not a major rule as defined in Executive Order 12291. The provisions of the interim final rule, including the codification of the criteria for determination of substantial equivalence, the 510(k) summaries and class III summaries should assist submitters in organizing their submissions by giving submitters a framework for organizing the discussion of substantial equivalence. The regulation may be used as a checklist by submitters whether they submit a summary or a certification. This should result in better submissions and more efficient review. FDA estimates that the annual cost of submitting 510(k) summaries or statements will be $1.135 million and the annual cost of submitting the requested information, if the statement option is chosen, will be $22,000. The total annual cost will be $1.157 million for the 510(k) summary/statement requirements. In addition, FDA estimates that the annual cost of submitting the class III summaries will be $1.2 million. All of these costs will be spread among several thousand marketers in any year. Therefore FDA certifies that the rule will not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act. A copy of the document supporting this determination is on file at the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

This rule itself is not a major rule, however, the cumulative effect of regulations promulgated under the SMDA may result in a major increase in costs for the device industry and/or have associated costs in excess of the $100 million threshold that defines a major rule. FDA specifically requests comments on the need to consider the regulations promulgated under the SMDA together as a major rule.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35). The title, description, and respondent description of the information are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: 510(k) Summaries and Statements Under Public Law 101–629—General Requirements.

Description: FDA is issuing a final rule to implement provisions of SMDA regarding the submission of summaries of safety and effectiveness information along with premarket notifications or a certification that the safety and effectiveness information will be made available to any person upon request. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on manufacturers. The existing information collections have been approved under OMB No. 0910–0120.

Description of Respondents: Manufacturers and importers of medical devices.

ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Summaries 807.87(h)	1,645	1	1,645	23	37,835
Statements 807.87(h)	3,055	1	3,055	.65	1,986
Citations 807.87(i)	500	1	500	42	21,000
Total					60,821

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this final rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

List of Subjects in 21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 807 is amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS OF DEVICES

1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 371, 374).

2. Section 807.3 is amended by adding new paragraphs (n), (o), (p), and (q) to read as follows:

§ 807.3 Definitions.

* * * * *

(n) *510(k) summary* (summary of safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(o) *510(k) statement* means a statement made under section 513(i) of the act, asserting that the information in a premarket notification submission regarding safety and effectiveness that supports a finding of substantial equivalence will be made available, upon request, to the public. The information to be made available includes adverse safety and effectiveness information but excludes patient identifiers.

(p) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(q) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the devices being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the types of problems to which the device is susceptible and the causes of such problems.

3. Section 807.87 is amended by redesignating paragraph (h) as paragraph (k) and by adding new paragraphs (h), (i), and (j) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which on final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

* * * * *

4. New §§ 807.92, 807.93, and 807.94 are added to subpart E to read as follows:

§ 807.92 Content and format of a 510(k) summary.

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the predicate or legally marketed device or devices to which substantial equivalence is being claimed;

(4) A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device such as device design, materials used, and physical properties;

(5) A statement of the intended use of the device, including a general description of the diseases or conditions the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate or legally marketed device identified in paragraph (a)(3) of this section, the summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device and why the differences do not affect the safety or effectiveness of the device when used as labeled; and

(6) A statement of how the technological characteristics of the device (i.e., design, material, chemical composition, or energy source) compare to those of the predicate or legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket notification submissions in which a determination of substantial equivalence is based on an assessment of performance data shall contain the following information in addition to the information required by paragraph (a) of this section:

(1) A brief discussion of the nonclinical tests and their results submitted in the premarket notification;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety and/or effectiveness data obtained with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is safe, effective, and performs as well as or better than the legally marketed device

identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."

§ 807.93 Format of a 510(k) statement.

A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that [name of person required to submit the premarket notification] will make available all information included in this premarket notification on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information I agree to make available does not include confidential patient identifiers.

(This statement should be made in a separate section of the premarket notification submission and should be clearly identified as a 510(k) statement.)

§ 807.94 Format of a class III certification.

A class III certification submitted as part of a premarket notification shall state as follows:

I certify that a reasonable search of all information known or otherwise available to (name of premarket notification submitter) about the types and causes of reported safety and/or effectiveness problems for the (type of device) has been conducted. I further certify that the types of problems to which the (type of device) is susceptible and their potential causes are listed in the attached class III summary, and that this class III summary is complete and accurate.

(This statement should be clearly identified as a class III certification and should be made in the section of the premarket notification submission that includes the class III summary.)

5. Section 807.95 is amended by removing paragraph (c)(3), by redesignating paragraph (d) as paragraph (e), and by adding new paragraph (d) to read as follows:

§ 807.95 Confidentiality of information.

* * * * *

(d) FDA will disclose publicly a premarket notification submitter's summary of the safety and effectiveness data on the device within 30 days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a manufacturer has complied with the conditions set forth in paragraphs (b) and (c) of this section, confidentiality for a premarket notification submission can not be granted beyond 30 days after FDA issues a determination of equivalency.

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Dated: December 6, 1991.

Editorial Note: This document was received by the Office of the Federal Register on April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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