events such as fires, explosions, and toxic gas releases).

(2) A defect in any spent fuel storage structure, system, or component which is important to safety.

(3) A significant reduction in the effectiveness of any spent fuel storage confinement system during use.

(4) An action taken in an emergency that departs from a condition or a technical specification contained in a license or certificate of compliance issued under this part when the action is immediately needed to protect the public health and safety and no action consistent with license or certificate of compliance conditions or technical specifications that can provide adequate or equivalent protection is immediately apparent.

(5) An event that requires unplanned medical treatment at an offsite medical facility of an individual with radioactive contamination on the individual's clothing or body which could cause further radioactive contamination.

(6) An unplanned fire or explosion damaging any spent fuel or HLW, or any device, container, or equipment containing spent fuel or HLW when the damage affects the integrity of the material or its container

(c) Non-emergency notifications: Twenty-four hour reports. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving spent fuel or HLW:

(1) Any unplanned contamination event that requires access to the contaminated area by workers or the public to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

(2) An event in which safety equipment is disabled or fails to function as designed when.

(i) The equipment is required by regulation, license condition, or certificate of compliance to be available and operable to prevent releases that could exceed regulatory limits, to prevent exposures to radiation or radioactive materials that could exceed regulatory limits, or to mitigate the consequences of an accident; and

(ii) No redundant equipment was available and operable to perform the required safety function

(d) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a), (b), or (c) of this section by telephone to the NRC Operations Center.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The quantities, and chemical and physical forms of the spent fuel or HLW involved; and

(v) Any personnel radiation exposure data.

(2) Written report. Each licensee who makes an initial report required by paragraph (a) or (b) of this section shall submit a written followup report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of 10 CFR Part 20. These reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The quantities, and chemical and physical forms of the spent fuel or HLW involved;

(iv) Date and time of the event,

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

3. Section 72.216 under Subpart K—"Reports"—is amended by adding new paragraph (c) to read as follows:

§ 72.216 Reports.

* * * * *

(c) The general licensee shall make initial and written reports in accordance with §§ 72.74 and 72.75, except for the events or conditions specified by §§ 72.75(a)(2) and (3) for which the initial reports will be made under paragraph (a) of this section.

Dated at Rockville, Maryland, this 30th day of November, 1994

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 94–30694 Filed 12–13–94; 8:45 am]

BILLING CODE 7590–01–P

[1] The commercial telephone number for the NRC Operations Center is (301) 816–5100.

INTERNATIONAL TRADE COMMISSION

19 CFR Part 210

Final Rules for Investigations and Related Proceedings Concerning Unfair Practices in Import Trade; Correction

AGENCY: United States International Trade Commission.

ACTION: Correction to final rules.

SUMMARY: This document contains corrections to the final rules which were published Monday, August 1, 1994 (59 FR 39020). The rules relate to practice and procedure under section 337 of the Tariff Act of 1930.

EFFECTIVE DATE: December 14, 1994.

FOR FURTHER INFORMATION CONTACT: Paul A. Newhouse, Esq., Office of Administrative Law Judges, U.S. International Trade Commission, telephone 202–205–2699. Hearing-impaired individuals can obtain information on the final rules by contacting the Commission's TDD terminal at 202–205–1810.

SUPPLEMENTARY INFORMATION:

Background

The final rules that are the subject of these corrections became effective August 31, 1994, and are applicable to all investigations and related proceedings under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) that are instituted after that date.

Need for Correction

As published, the final rules contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication on August 1, 1994 of the final rules, which were the subject of FR Doc. 94–17643, is corrected as follows:

1. On page 39042, in the first column, in § 210.4(d)(3), the reference to "§ 210.25 (d) and (f)" is corrected to read "§ 210.25(d)–(f)"

2. On page 39044, in the third column, in § 210.12(a)(9)(i), the word "complainant" is corrected to read "complaint"

3. On page 39065, in the third column, in Appendix A to § 210 68, in

item 8, the term "real state" is corrected to read "real estate", and in instruction 2, the quotation mark preceding the word "National" is removed.

Issued: December 8, 1994.

By Order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–30725 Filed 12–13–94; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to implement the provisions of the Safe Medical Devices Act of 1990 (the SMDA) that require all persons who submit a premarket notification (510(k)) to provide to FDA, as part of the submission, an adequate summary (510(k) summary) of any information respecting safety and effectiveness or a statement (510(k) statement) that such information will be made available upon request by any person. This rule also implements the requirement of the SMDA 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, this rule amends the device regulations governing the confidentiality of certain premarket notification submissions to conform to the SMDA. This rule also provides that persons who submit a premarket notification must certify that, to the best of their knowledge, all information is truthful and accurate and that no material fact has been omitted.

EFFECTIVE DATE: March 14, 1995.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 28, 1992 (57 FR 18062), FDA issued an interim rule implementing the provisions of the SMDA that require persons who submit premarket notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) to 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. The interim rule also implemented 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 certify (class III certification) that they have conducted a search of safety and effectiveness data concerning the device and submit a summary of, and a citation to, all adverse safety and effectiveness information respecting the device (class III summary). In addition, the interim rule amended the device regulations governing the confidentiality of certain premarket notification submissions to conform to the SMDA. The interim rule also provided that persons who submit a premarket notification must certify that the data and information are truthful and accurate and that no material fact has been omitted. FDA stated that the interim rule would become effective on May 28, 1992.

Interested persons were given until June 29, 1992, to comment on the interim rule. In the **Federal Register** of June 1, 1992 (57 FR 23059), this comment period was extended until August 27, 1992, in response to a petition filed by a trade association. The effective date was stayed by FDA until the comments were reviewed and a new rule was published and made effective.

II. Comments

The agency received 19 comments from trade associations, manufacturers, a supplier, and a medical device consultant. A summary of the comments and the agency's response to them is provided below:

1. One comment from a manufacturer questioned why § 807 87(i)(2) (21 CFR 807.87(i)(2)) of the interim rule stated that information that already has been submitted to FDA under section 519 of the act (21 U S.C. 360i) is not the type of information that would be included in a class III summary Section 519(a) of the act (21 U S.C. 360i(a)) authorizes FDA to issue regulations requiring the manufacturers of devices to maintain and provide records to ensure that devices are not adulterated, misbranded, unsafe, or ineffective.

The SMDA (513(f)(3)) of the act (21 U.S.C. 360c(f)(3)) specifically excludes all adverse safety and effectiveness data that have been submitted to FDA under section 519 of the act from class III summaries (summaries submitted by manufacturers claiming substantial equivalence to a class III preamendments device for which FDA has not yet called for a PMA). Although the statute does not require manufacturers to submit such data more than once, the agency understands that a class III summary may include information that has previously been submitted under section 519 of the act.

2. Many comments argued that the certification requirement in § 807.87(j) of the interim rule should be deleted because FDA can utilize existing programs and statutes to ensure that erroneous information is not submitted to the agency One comment further argued that FDA cannot require the regulated community to certify the completeness of any 510(k) submission because that completeness is subject to a variety of interpretations.

As noted in the preamble to the interim rule, this certification requirement was added in response to a July 1990 report by the Office of the Inspector General (OIG) on internal controls covering the 510(k) review process. In that report, the OIG stated that, "because the generic drug approval scandal has raised concern about industry's behavior under the so-called 'honor system,' we believe that the 510(k) process needs a program to help ensure that what industry reports on paper is in fact accurate." The OIG recommended requiring industry to certify the accuracy of data submitted in 510(k) submission documents in order to enhance the integrity of the 510(k) premarket notification process. (See page 22 of OIG report). The agency believes that such a requirement provides additional assurance that the data submitted are complete and accurate. However, in response to the comment that concerned the inability of any individual to know if information is complete, FDA has modified the language in § 807.87(j) to include the phrase "to the best of his or her knowledge." This certification should be made by an industry representative, preferably the official correspondent of the firm.

3 Several comments complained that FDA improperly expanded the scope of the information required by the SMDA for summaries "of any information

respecting safety and effectiveness" by requiring such summaries to contain "data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information." A few comments noted that FDA's decision to treat all information submitted in support of a substantial equivalence determination as "safety and effectiveness" information seems contrary to the notion that "substantial equivalence" determinations are, on their face, determinations of 'equivalence," and not of safety and effectiveness. One comment cited an FDA publication on 510(k) requirements, which stated, "The purpose of data, such as clinical data, for a premarket notification submission is to demonstrate that the device is equivalent in performance to the preamendments device. FDA does not intend that the data determine the device's safety and effectiveness." See "Premarket Notification: 510(k) Regulatory Requirements for Medical Devices," HHS Publication FDA 90–4158, August 1990, p. 2. Another comment stated that information concerning device design, intended use, or technological characteristics is useful information which may support a determination of substantial equivalence, but may not support a determination of safety and effectiveness.

FDA believes that Congress clearly intended the concept of "substantial equivalence" to include some inquiry into the safety and effectiveness of a new device, and that such inquiries into safety and effectiveness are often inseparable from other bases of determining substantial equivalence. The Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 (House Report) indicates that "substantial equivalence" is to be assessed not only in relation to physical characteristics and intended use, but sometimes also in terms of safety and effectiveness. The committee believed that the term "substantially equivalent" "should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness." (H. Rept. No. 94–853, p. 36.)

The 1976 amendments, therefore, provided FDA with statutory authority to consider the safety and effectiveness of a device when determining whether such a device is substantially equivalent to a predicate device. The legislative history of the 1990 amendments states Congress' express intent to codify FDA's interpretation of the term "substantial equivalence," including the agency's determination that substantial equivalence requires a finding of comparable safety and effectiveness (S. Rept. 513, 101st Cong., 2d sess. 41 (1990)). Accordingly, § 807.3 (21 CFR 807.3), which defines a 510(k) summary to be "a summary * * * of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based" merely codifies the agency's long-standing interpretation, approved by Congress, that safety and effectiveness can be an integral part of a substantial equivalence determination. The agency has concluded, therefore, that the requirement that summaries of safety and effectiveness data include information supporting a finding of substantial equivalence is consistent with legislative intent and agency practice.

4. One comment stated that FDA should revise the language on page 18062 of the interim rule which reads, "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," to read as follows: "FDA's decision regarding the existence of substantial equivalence will be based on all the information contained in a 510(k)." This comment believed that the 510(k) summary is intended to be a synopsis of safety and effectiveness information for requestors, and is not intended for the use of FDA reviewers when arriving at determinations of substantial equivalence. Therefore, this comment suggested that the phrase "510(k) safety and effectiveness summary" be inserted in lieu of the term "510(k) summary" throughout the rule.

FDA agrees in part with this comment. As stated in the interim rule, 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. However, the agency does not agree that a change in terminology would significantly increase the clarity of the rule and does not believe that the term "510(k) summary" needs to be replaced with "510(k) safety and effectiveness summary" throughout the rule.

5. One comment stated that the portion of the 510(k) summary required in § 807.92(a)(5) (21 CFR 807.92(a)(5)), "statement of intended use," should include definitions of the differences between the submitter's new device and the legally marketed device, if the indication statements are not the same. This comment further stated that the brief discussion of nonclinical tests required as part of the 510(k) summary under § 807.92(b)(1) should include references. The comment further stated that the requirement should state clearly that conclusions drawn from test results should compare the device with legally marketed devices (§ 807.92(a)(3)).

The agency agrees in part with this comment. FDA believes that the interim rule required sufficient detail about the intended use of the device and its predicate. However, the agency has revised § 807.92(a)(5) on intended use to clarify that substantial equivalence claims can only be made to predicates that are legally marketed. With respect to the comment that conclusions from test results should compare the device with legally marketed devices, § 807.92(b)(3) does require "conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device * * *." Therefore, no revision of this provision is warranted.

6. One comment recommended that 510(k) summaries need include only information required by § 807.92(b)(3), which concerns conclusions drawn from nonclinical and clinical tests that demonstrate comparable safety, effectiveness, and performance of a new device to a legally marketed device, as intended by Congress. Another comment also recommended reducing the amount of information required in a 510(k) summary, noting that information of a descriptive nature is sufficient in most cases to allow a determination of substantial equivalence. This comment argued that requiring 510(k) summaries to include clinical and preclinical data in cases where such data are not necessary, would require needless and costly data preparation and FDA review.

The agency has always required 510(k) submissions to include descriptive data that are necessary to understand the indication, physical composition, method of operation, specifications, or performance claims of the device. Also, the agency has always required any descriptive data about the legally marketed device that are necessary to understand the characteristics of the device to which the new device is being compared. A legally marketed device to which a new device may be compared is a predicate device (device legally marketed prior to May 28, 1976, or a device which has been classified from class III to class II or class I), or a device which has been

found to be substantially equivalent through the 510(k) premarket notification process. In order to clarify the definition of a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence, the agency is amending § 807.92(a)(3) to include this definition of a legally marketed device.

The new requirement for 510(k) summaries does not change or add to the type of information that must be included in a 510(k) submission. However, FDA has modified the language of § 807.92(a)(4) to clarify that descriptive information required for a 510(k) summary is expected to be a condensed and summarized version of information in a 510(k) submission, similar to labeling or promotional descriptions.

To date, the agency has required or used clinical investigation data in less than 10 percent of its premarket notification submissions. The agency generally requires clinical data when the description of a new device indicates an important difference in comparison to marketed devices within its type, i.e., new material or method of operation of the new device. The agency may also require performance data when descriptive characteristics of the new device are not sufficiently precise to ensure that the new device, when manufactured according to its description, will be comparable to the legally marketed device.

The legislative history of the SMDA explicitly supports FDA's practice of requesting additional data in this regard in order to determine substantial equivalence.

> The determination of comparable safety and effectiveness is at times easy, where the newer device and its predicate use the same technologies. More difficult judgments occur when the technologies of the devices differ. In this latter situation, FDA will not make a substantial equivalence determination without data, including clinical data, that demonstrates comparable safety and effectiveness (S. Rept. 513, 101st Cong., 2d sess. 28 (1990)).

7. One comment suggested that the agency release the entire 510(k), excluding trade secret and specific patient information, in lieu of requiring safety and effectiveness summaries. In the alternative, this comment suggested making the information required by § 807.92(b) part of the 510(k) cover letter supplied by the 510(k) submitter, and then making the entire cover letter releasable because that letter would ordinarily include the information requested in § 807.92(a).

The agency disagrees. The release of either the entire 510(k), excluding trade secret information and patient identifiers, or release of the 510(k) cover letter, in lieu of the 510(k) submitter's 510(k) summary would be inconsistent with the SMDA. Section 513(i) of the SMDA expressly requires 510(k) submitters to submit summaries of information that are intended for public disclosure respecting safety and effectiveness or to state that such information will be made available upon request by any person (21 U.S.C. 360c(i)(3)). There is no basis in the legislation to require FDA to create summaries or substitutes for summaries. However, if 510(k) submitters choose to have the entire 510(k), excluding patient identifiers and trade secret and confidential commercial information, released in lieu of a 510(k) summary, they may elect to submit a 510(k) statement and then release that information themselves in response to requests from the public.

A. Trade Secret/Confidential Information

8. A few comments stated that FDA is precluded by the Freedom of Information Act (the FOIA), 5 U.S.C. 552, and the act from divulging trade secret information. Many comments believed that virtually all of the technological information required by the interim rule to be made public can qualify as trade secret information, even under the narrow definition of "trade secret" adopted by the D.C. Court of Appeals in *Public Citizen Health Research Group* v. *Food and Drug Administration*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). Specifically, these comments argued that the "signifioant physical and performance characteristics of the device such as device design, materials used, and physical properties," constitute a commercially valuable plan, formula, or process. Similarly, the chemical composition of various reagents and controls, to the extent that nonactive ingredients are involved, would also implicate the types of information that are normally closely guarded as trade secrets by a 510(k) submitter.

The agency does not intend that submitters include trade secret or confidential commercial information in the 510(k) summaries, which Congress expressly intended for public disclosure. In addition, "the using by any person to his own advantage, or revealing, other than to * * * the Department, or to the courts * * * any information acquired under authority of section * * * 510 * * * concerning any method or process which as a trade secret is entitled to protection" is prohibited under the act. (See section 301(j) of the act (21 U.S.C. 331(j))). The requirements set forth in § 807.92(a)(4) and (a)(6) have been modified to reflect the agency's intention that trade secret and confidential commercial information be protected. For example, the agency now states in § 807.92(a)(4) that information concerning a device's description may be information that a firm would disclose in its device labeling or promotional material. The term "statement" in § 807.92(a)(6) has been replaced with "summary" to reflect the agency's expectation that information provided concerning technological characteristics will be provided in summary fashion, in a form that is clear, concise, and adequate, but not so detailed as to disclose trade secret information. As stated in the interim rule, if a premarket notification submission contains only descriptive information to support substantial equivalence, the 510(k) summary for that submission would be required to contain only general information about the device and a summary of the descriptive information that demonstrates the new device is as safe and effective as the device to which the sponsor is requesting substantial equivalence.

If a 510(k) submitter, however, fails to comply with the provisions concerning 510(k) summaries or 510(k) statements, the agency may provide the public with a purged copy of the 510(k) submission prepared by agency staff. Under these circumstances, FDA would not follow predisclosure notification procedures established for responses to FOIA requests for 510(k) records.

9. One comment stated that because the interim rule transcends the provisions of the FOIA, there must be an independent legal basis authorizing disclosure of trade secret information prohibited from release by the Trade Secrets Act (the TSA), 18 U.S.C. 1905. Citing *Chrysler Corp.* v. *Brown*, 441 U.S. 281 (1979), this comment argued that while "properly promulgated, substantive agency regulations have the 'force and effect of law'," an interpretative regulation does not have the force and effect of law necessary to obviate the restrictions in the TSA. Id. at p. 295 and 302. Thus, for agency action to qualify as "authorized by law," under TSA, "* * * it must have certain substantive characteristics and be the product of certain procedural requisites." Id. at p. 301. This comment noted that, in the preamble to the interim rule, FDA concluded that the regulation is not a substantive rule. Therefore, this comment argued, the regulation cannot qualify as a regulation authorized by law under the TSA.

Furthermore, the comment continued, even if the interim rule had been labeled a substantive rule, it would still not have the "force and effect" of law because it was signed by the Acting Deputy Commissioner for Policy who lacks authority to unilaterally issue rules under either the TSA or the FOIA.

The agency disagrees. FDA's statutory authority for requiring disclosure of particular information in a 510(k) summary is section 513 of the act, in which Congress expressly required release to any person of such summaries. Congress also specifically authorized the Secretary of the Department of Health and Human Services (the Secretary) to establish the content of those summaries. The agency, therefore, believes that a regulation promulgated to implement that section may provide proper authorization for disclosure.

However, whether or not the analysis set forth in the comment submitted to the agency is correct, the objections raised by that comment are now irrelevant. As explained above, FDA does not expect 510(k) summaries to include trade secret or confidential commercial information. In addition, the agency is modifying its statement, in the interim rule, that a dispute over the adequacy of information provided by a 510(k) statement submitter should require the release to the requestor of confidential commercial information that is also considered safety and effectiveness information. The agency has concluded that a dispute over the adequacy of information provided in support of a 510(k) statement should not require automatic disclosure by the submitter of information that is properly protected from public release. However, if the agency determines that a submitter is attempting to undermine the 510(k) statement process by providing information to requestors that is untimely or inadequate, such actions will be deemed a prohibited act under section 301(q)(2) and (p) of the act, and the agency will use a variety of means, including its enforcement tools, to end violations. For example, in response to valid complaints from requestors, FDA may choose to make purged copies of the 510(k) publicly available. (See also section III. of this document).

10. One comment stated that FDA's apparent abandonment of any effort toward confidentiality raises serious concerns about proprietary interests, intellectual property protection, liability issues, and market timing. Indeed, another comment argued that the disclosure of trade secret or confidential information results in a taking without just compensation.

As noted in paragraphs 8 and 9 of this document, FDA recognizes its obligation to protect information that is exempt or prohibited from public disclosure, and the agency does not expect 510(k) summaries to include such information.

11. A few comments stated that the interim rule will compel small manufacturers to seek costly patent protection and discourage innovation. One comment noted that many small entrepreneurs believe that the expense of seeking patent protection is not warranted if the characteristics of an otherwise patentable invention cannot be easily ascertained through reverse engineering. However, this comment continued, the effect of the interim rule would compel these small, start-up companies to seek expensive and unnecessary patent protection to protect trade secrets.

This final rule clarifies FDA's position that trade secret and confidential commercial information need not be included in a 510(k) statement or 510(k) summary. The agency takes this opportunity, however, to remind manufacturers and submitters of 510(k)'s that details about manufacture, composition, specification, performance, and testing that are included in labeling or promotional materials cannot be considered confidential under any circumstances.

B. 510(k) Summaries and Predisclosure Notification

12. One comment disputed the notion that information contained in a 510(k) submission is exempt from predisclosure requirements set forth in Executive Order 12600. This comment believed that this exemption should apply only to the information contained in a 510(k) summary, rather than to the information contained in the actual 510(k) submission. This comment maintained that a submitter should be afforded the opportunity to submit a 510(k) summary prior to disclosure of the information contained in a 510(k) submission.

FDA agrees. The premarket notification submission ordinarily is subject to predisclosure notification under Executive Order 12600. However, 510(k) summaries are prepared by submitters who know that these summaries are intended for public disclosure. In light of the statute and the agency's implementing regulation, submitters can have no reasonable expectation that such documents will be withheld. Accordingly, it would be unnecessary and inappropriate to subject 510(k) summaries to predisclosure notification. It is the 510(k) submitter's obligation to prepare either a 510(k) summary of any information respecting safety and effectiveness or provide a 510(k) statement that the 510(k) submitter will make such information available upon request.

With respect to the decision about whether to submit a 510(k) summary or 510(k) statement, FDA is correcting the statement in the preamble to the interim rule that this decision by the 510(k) submitter may not be changed once the 510(k) submission has been received by FDA. Instead, FDA now clarifies that a 510(k) submitter who elects to submit a 510(k) summary when the premarket notification submission is filed, may, before a substantial equivalence determination is reached, submit either a revised 510(k) summary or a 510(k) statement in lieu of the 510(k) summary. Likewise, a 510(k) submitter who elects to submit a 510(k) statement when the premarket notification submission is filed, may, before the substantial equivalence determination is reached, submit a 510(k) summary in lieu of the 510(k) statement.

C. 510(k) Statements

13. Several comments said that § 807.93 (21 CFR 807.93) places a manufacturer who submits a 510(k) statement at risk to provide all information, including trade secret or confidential commercial information that relates to safety and effectiveness. Indeed, FDA specifically concluded that manufacturers could not withhold such information (see 57 FR 18062 at 18064).

The interim rule specifically requested comments on this issue and, as noted above, the agency has changed its earlier interpretation.

14. A few comments noted that there is no rational basis for FDA to treat 510(k) statements differently than 510(k) summaries for confidentiality purposes. These comments asserted that Congress provided two distinct options for 510(k) submitters in the SMDA, the 510(k) summary or the 510(k) statement. However, if FDA continues with its current interpretation, the 510(k) statement undoubtedly would fall into disuse because 510(k) submitters would choose not to release their trade secret or confidential commercial information. Another comment stated that FDA should clearly state that the selection of a 510(k) statement by the submitting firm should be equally acceptable to the agency and should not adversely affect the review process of the 510(k).

FDA agrees with these comments. The SMDA was not intended to deter the submission of a 510(k) statement. Indeed, it provided 510(k) submitters with two alternatives. The disparate

treatment of the 510(k) statement and 510(k) summary for confidentiality purposes in the interim rule was incorrect. However, while FDA can implement disclosure of 510(k) summaries that have been filed with the agency, FDA does not have similar control over disclosure of information promised by 510(k) statements. As stated above, noncompliance with the commitment made in a 510(k) statement will be deemed prohibited acts under section 301 (q)(2) and (p) of the act and FDA will use its enforcement powers to obtain compliance.

15. One comment stated that the certification language in § 807.93 contradicts FDA's prior advice concerning 510(k) statements. The comment noted FDA's previous statement that 510(k) statements should be submitted instead of 510(k) summaries until FDA determined the content of 510(k) summaries, and FDA's previous statement that trade secret and confidential commercial information contained in a 510(k) that was the subject of a 510(k) statement need not be disclosed to the public. Another comment stated that fairness required the agency to clarify that the 510(k) submitters who relied on existing laws and regulations, and on previous FDA advice concerning confidentiality prior to the effective date of any interim rule changing such protections, are entitled to withhold trade secret and confidential commercial information.

FDA believes the concerns raised by this comment have been addressed above. As noted in response to previous comments, the agency does not intend to require 510(k) submitters to make public disclosures of true trade secret or confidential commercial information.

16. Several comments proposed changes to the wording for certification of 510(k) statements under § 807.93. One comment suggested: "I certify * * * will make available all information included in this premarket notification on safety and effectiveness, except trade secret and/or confidential information, that supports a finding of substantial equivalence * * *."

Other comments suggested revising § 807.93 to read as follows:

> I certify that (contact person for the premarket notification) will make available all information included in this premarket notification on safety and effectiveness as identified in § 807.92 of this rule that supports a finding of substantial equivalence within thirty (30) days of request by any person. The information I agree to make available does not include confidential patient identifiers.

FDA has incorporated elements of all these comments into the final rule. The agency has modified the certification requirement so that it is consistent with FDA's regulations prohibiting the disclosure of trade secret and confidential commercial information. The statement also has been changed to clarify that the commitment to release information only becomes effective after a device has been determined to be substantially equivalent. The agency has also amended the certification language in § 807.93 to reflect FDA's expectation that the official correspondent in the firm will prepare the certification on behalf of the firm.

The certification now states:

> I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.

17. The agency received comments that indicated uncertainty about the scope of the obligation of a 510(k) statement submitter to respond to requests for safety and effectiveness information that are made after the ownership of the 510(k) has changed, the device is no longer marketed, or the firm is no longer in business.

The legislative history of the SMDA is silent on this issue. The agency has concluded that the firm submitting the 510(k) statement has a continuing obligation to comply with the 510(k) statement commitment, unless the firm relieves itself of this obligation by requiring the new 510(k) holder to submit a 510(k) statement in accordance with § 807.93 to the agency in the situation where there has been a transfer of ownership of a 510(k). In those cases, the original 510(k) holder should inform any requesters of the transfer of obligation that accompanied the transfer of ownership. If a firm ceases to market the device, but continues to do business, it must continue to comply with requests for information. However, if the firm goes out of business and there has been no transfer of ownership, the agency will, upon sufficient written notification, relieve the firm of its obligation to honor requests for safety and effectiveness information from the premarket notification submission. Under these circumstances, FDA will release the entire premarket notification submission excluding patient identifiers and any information that remains trade secret or confidential commercial information.

18. Another comment suggested that the regulation identify the kinds of documents that the public may have access to when requesting safety and effectiveness information from a 510(k) statement submitter. This comment noted that this could be accomplished by codifying the statement in the preamble, "FDA believes that the information a submitter is required to furnish should be taken only from the information contained in the premarket notification submission."

FDA believes that the concern raised by this comment has been addressed by the change in the language of § 807.93. That regulation clearly restricts the obligation of a 510(k) submitter to provide only information that is contained in the premarket notification. The regulation requires 510(k) holders who submit statements to provide requestors with a duplicate of their premarket notification submission, including any adverse information, but excluding patient identifiers and trade secret or confidential information. (See 21 CFR 807.93(c)). FDA believes that the establishment of this procedure for 510(k) statement submitters is in furtherance of the act. The regulation ensures that disclosures will be uniform to all requesters, that preparation of the information for disclosure need be done only one time by the submitter, and that confidential commercial and trade secret information remains protected. FDA notes that 510(k) submissions for any device found to be substantially equivalent have been available to the public under the FOIA since 1976.

19. One comment stated that FDA should permit a 510(k) statement to appear without any certification language, using a format such as the following: "Information in this 510(k) respecting safety and effectiveness will be made available upon request by any person." Another comment noted that section 513(i) of the statute does not require this statement to be made in the form of a "certification."

Although the statute does not expressly require "certification," FDA does not agree that certification language should be eliminated from the 510(k) statement. The agency believes that certification provides additional assurance that submitters will comply with their statutory obligations.

D. Timeframes

20. A couple of comments argued that there is no basis for the agency's choice

of a 30-day time limit for 510(k) statement submitters to respond to requests for safety and effectiveness information. One comment requested that FDA revise this timeframe to 90 days. Other comments noted that there is no indication that the agency has considered the burden that such a timeframe imposes upon a submitter, or whether the burden could be offset by charging requesters for the review time, assembly time, duplication, and mailing of the information.

FDA believes that the equal choice provided by the statute for 510(k) submitters to submit either 510(k) summaries or 510(k) statements indicates the intent of Congress that information should be available to requesters at the same time after a finding of substantial equivalence, without regard to the 510(k) submitter's choice of 510(k) summary or 510(k) statement.

The agency has determined that imposing a 30-day timeframe on 510(k) statement submitters is not unduly burdensome. The agency expects that 510(k) submitters who elect to file 510(k) statements will begin purging the 510(k) submission at the time they file their premarket notification submission.

The agency recognizes that some firms that currently have a 510(k) under review may not have purged copies of their 510(k) submissions ready for disclosure. Section 519(a)(i) of the act states that FDA shall not impose requirements unduly burdensome to a device manufacturer, taking into account the cost of complying with such requirements and the need for protection of the public health and the implementation of the act. The agency is establishing an effective date of 90 days for this final rule. The agency believes that this will give 510(k) statement submitters whose 510(k)'s are under review, sufficient time to prepare this information. After the 90 days have elapsed, the agency will expect companies to comply with requests for information within 30 days of receiving such requests.

The agency believes that 510(k) submitters may not charge requestors for compiling and disseminating the data because such charges would be inconsistent with congressional intent. Charges to requestors could discourage disclosure of information Congress has determined should be made available to the public. In addition, it would be difficult for the agency to determine or monitor reasonable fees for disclosure by 510(k) submitters. If a 510(k) submitter decides that the preparation and dissemination of this information is too costly, the firm may elect to submit a 510(k) summary in lieu of a 510(k) statement. A 510(k) summary can be submitted to the agency in lieu of a 510(k) statement at any time before the substantial equivalence determination is made. In that case, costs associated with release of information to requestors will be standardized and implemented by FDA.

21. Another comment suggested that the timeframe for providing requestors with safety and effectiveness data in support of a substantial equivalence determination should be 30 business days, rather than 30 calendar days, and that all requests should be addressed in writing to the official correspondent of the company. This comment also suggested that the agency include language in the regulation that would prohibit disclosure of this information to a company's competitors without a substantiating justification. The comment also stated that the rationale for the request should be known to the company, and that all costs associated with the request should be borne by the requestor.

The agency has determined that 30 calendar days, rather than 30 business days, is an appropriate timeframe because it is FDA's expectation that such information will be prepared at or near the time of the premarket notification submission. (See FDA's response to comment 26 of this document). FDA also disagrees with the suggestion that the agency's regulation should limit access to the data. There is no provision in the statute that requires requestors to provide a rationale for making their request for safety and effectiveness information, or precludes them from sharing this information with any other person, including competitors. Indeed, under FDA's current regulations, the contents of a 510(k) submission are available for public disclosure after FDA makes a determination of substantial equivalence, so long as patient identifiers, trade secret, and confidential commercial information are deleted. Such disclosures under the FOIA are made without regard to the purpose or identity of the requestor.

The new regulation, therefore, is entirely consistent with current agency disclosure practices and should be familiar to many companies who have previously prepared 510(k) submissions for public disclosure. The agency believes that these final regulations and FDA's other public information regulations protect trade secret and confidential commercial information from public disclosure by providing 510(k) submitters the opportunity to delete proprietary information from their records. Accordingly, competitors will not gain an unfair competitive advantage when 510(k) statement submitters release the information they have pledged to disclose.

FDA does agree that all requests for information should be made to the official correspondent of the company or the person whose name appears on the list of premarket notification submissions found substantially equivalent. This list is available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. The agency believes that directing the request to one person within the firm will expedite the dissemination of this information. The agency has modified § 807.93(b) accordingly. The issue of payment by requestors of information to 510(k) submitters who have made 510(k) statements has been addressed previously in paragraph 21 of this document.

E. Class III Summaries and Certifications

22. Many comments argued that the statute only requires a "class III summary" to include information about the predicate device referenced in the 510(k), and not about the generic type of device. Another comment noted that a search for and summary of adverse safety and effectiveness data concerning a generic device type will yield substantial information that is not relevant to the 510(k) device or to its predicate device(s), because design and functional variations can make comparisons within an entire device type meaningless. These comments believed that FDA should limit the search and summary requirements to the device that is the subject of the 510(k) and its predicate device(s), as Congress intended.

FDA disagrees with this interpretation of the statute. Section 513(f)(3)(C) states that "the manufacturer shall certify * * * that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included * * * a summary of and a citation to all adverse safety and effectiveness data respecting such other device * * *." FDA's requirement to include information concerning the "type of device" is consistent with the language in the statute which requires that "all" adverse safety and effectiveness data be submitted. Furthermore, determinations regarding substantial equivalence frequently require FDA to compare the safety and effectiveness information for

a new 510(k) submission with the safety and effectiveness information concerning another device that has been found substantially equivalent through the 510(k) premarket notification process. (See 21 U.S.C. 360(i)(1)(A)). If the agency limited the scope of the class III summary only to information concerning the predicate chosen by the submitter, firms might fail to become aware of relevant safety and effectiveness problems associated with the type of the device they wish to market, including devices that have been found substantially equivalent. In addition, the agency might not obtain other information relevant to determining substantial equivalence.

23. Many comments stated that § 807.94 (21 CFR 807.94) requires the manufacturer to certify not only that he has conducted a reasonable search for adverse safety and effectiveness information, but also that he has absolutely included all such information in the summary. These comments pointed out that a manufacturer could never know with certainty that the information is complete or accurate, and therefore would become subject to new and personal criminal liability based on factors beyond his knowledge or control.

In response to these concerns, the agency has modified § 807.94 to clarify that the class III certification is being made by the individual on behalf of the firm who submitted the 510(k) and that the class III summary is complete and accurate "to the best of (the certifier's) knowledge."

F. 21 CFR 807.95—Confidentiality of Information

24. Many comments stated that FDA should revise the confidentiality section of the regulation to allow manufacturers to preserve the confidentiality of their 510(k) submission until the company is ready to begin marketing the device. These comments contended that this could be accomplished by granting manufacturers a provisional determination of substantial equivalence, leaving the final determination until the manufacturer is ready to market the device. One comment noted that, previously, a submitter provided certification and was able to maintain the confidentiality of its intention to market a device until such time as the device was actually ready to be commercialized. This comment further stated that the public disclosure of information about new devices as mandated by Congress is of potential importance only when a device is in a position to be marketed—a date which may be later than the 30 days after a determination of substantial equivalence has been made.

Another comment noted that it is unlikely that a device manufacturer would make an early submission for a premarket notification if it knows that competitors might gain access to confidential product and marketing information. As a result, the premarket notification process would be lengthened because submitters would wait to make such submissions in order to prevent others from gaining a competitive edge. This comment asserted that even though the SMDA requires FDA to make certain information available about a 510(k) notification within 30 days of a substantial equivalence determination, this does not mean that confidentiality under § 807.95(c) cannot be maintained.

FDA acknowledges that, in the past, manufacturers could request that a 510(k) clearance remain confidential until the device was actually marketed. However, the agency can no longer provide such extended confidentiality because of the statutory requirement that 510(k) summaries be available to the public within 30 days of the issuance of a determination that such device is substantially equivalent to another device. Even if the alternative suggested were more practical, the agency believes it lacks authority to extend this timeframe to the date a 510(k) submitter expects to begin marketing.

G. Procedures

25. One comment suggested that FDA consider formalizing administrative procedures by which companies submit premarket notifications, by which FDA reviews original premarket notifications and subsequent amendments thereto, and by which substantial equivalence orders are issued. Another comment contended that the issuance of formal administrative procedures would significantly "balance the playing field" for FDA management, for FDA reviewers, and for industry.

Administrative procedures are in place for submission, management, and review of premarket notifications. (See part 807 (21 CFR part 807) subpart E). FDA agrees that educational efforts concerning these procedures should be continued. The agency has issued numerous regulatory, guidance, and policy documents concerning premarket notifications and will continue to issue similar documents. These documents are available through the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance. In addition, it is the agency's expectation that this final rule will further clarify the requirements for premarket notification 510(k) summaries and 510(k) statements.

26. One comment requested FDA to provide an amendment process for 510(k) summaries that would permit the submitter of a 510(k) summary to amend it at any point in the review of the 510(k) prior to FDA's determination of substantial equivalence.

FDA will accept amendments to 510(k) summaries until such time as FDA makes a determination of substantial equivalence and has amended § 807 92(a) to state this policy Additionally, firms that elect to submit 510(k) statements at the time they file the premarket notification may change their minds and submit a 510(k) summary before the substantial equivalence determination is made. (See also response to paragraph 13 of this document).

H. Miscellaneous

27 One comment from a manufacturer noted that, in the preamble to the interim rule, a change in material would be considered a significant difference for purposes of determining substantial equivalence (see 57 FR 18062 at 18063). The comment stated that not all changes in materials are "significant." The comment further stated that the interim rule provided no guidance or formal procedures that would be applied to demonstrate equivalence or determine what constitutes a significant change The comment contended that existing § 807.87(g) appropriately addresses the issue of significant change.

FDA agrees that there are existing regulations that address the definition of "significant change." The agency believes that the criteria for a "significant change" are set forth in § 807.81(a)(3) (21 CFR 807.81(a)(3)). In addition, examples of what constitutes a significant change, as well as a detailed discussion of FDA's decisionmaking process for 510(k) applications, is contained in "FDA's Guidance on the Premarket Notification Review Program" and FDA's recent draft guidance, "Deciding when to submit a 510(k) for a change to an existing device." These publications are 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

The regulation that is the subject of this rulemaking is not intended to supplant current regulations and guidelines concerning significant

change. The new regulation builds on existing regulations and guidance in order to implement the section of the SMDA that directs the Secretary to establish the requirements for 510(k) summaries under section 513(i)(3)(B) of the act.

I. Effective Date

28. One comment stated that 60 days after date of publication is a reasonable effective date for the interim rule. Other comments argued that more time would be needed, particularly for companies who utilize the 510(k) statement and need to be in a position to comply with the 30-day timeframe for responding to requestors.

The agency is establishing a 90-day effective date after date of publication for all provisions in this rule, for the reasons discussed in paragraph 20 of this document.

III. Enforcement

FDA emphasizes that it is the 510(k) submitter's responsibility to prepare adequate 510(k) summaries, or to respond appropriately to requests for information from the public when the submitter has chosen to submit a 510(k) statement. If FDA determines that a submitter of a 510(k) summary or 510(k) statement has failed to comply properly with these regulations, FDA may provide the public with a purged copy of the 510(k) submission prepared by agency staff. Under these circumstances, FDA would not follow predisclosure notification procedures established for responses to FOIA requests for 510(k) submissions. Failure to comply with the requirements established by section 513(i) of the SMDA is a prohibited act under section 301(q)(2) and (p) of the act, and the agency will use its enforcement powers to deter noncompliance. Violations under section 301 of the act may be subject to seizure or injunction pursuant to sections 302(a) and 304(a) of the act (21 U.S.C. 332(a) and 334(a) respectively). In addition, a 510(k) submitter responsible for violating section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a) of the act (21 U.S.C. 333(a)).

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. Analysis of Impacts

An analysis of the costs and benefits of this regulation, conducted under Executive Order 12291, was discussed in the interim rule and the substance of that analysis has not changed. Executive Order 12291 has been superseded by Executive Order 12866.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The provisions of the final rule, including the codification of the content requirements for 510(k) summaries, 510(k) statements, class III summaries, and class III certifications 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 whenever they submit a 510(k) summary, a 510(k) statement, a class III summary, or a class III certification. This should result in better submissions and more efficient review. The costs of the rule will be spread among several thousand marketers in any year. For these reasons, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1980

Sections 807.87(h) and 807.87(i) of this final rule contain reporting requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0281 and are in conformance with the Paperwork Reduction Act of 1980 (44 U.S.C. Ch. 35). The annual burden for reporting is as follows:

ANNUAL BURDEN FOR REPORTING

CFR section	No. of respondents	No. 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

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, the interim rule amending 21 CFR part 807, which published in the **Federal Register** of April 28, 1992 (57 FR 18062), and stayed at 57 FR 23059, is adopted effective March 14, 1995 as a final rule with the following changes:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS 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, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

2. Section 807.3 is amended by revising the first sentence of paragraph (n) and paragraphs (o) and (q) to read as follows:

§ 807.3 Definitions.

* * * * *

(n) *510(k) summary* (summary of any information respecting 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 * * *.

(o) *510(k) statement* means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in § 20.61 of this chapter.

* * * * *

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

3. Section 807.87 is amended by revising the first sentence of paragraph (i)(2) and paragraph (j), and by adding a parenthetical statement at the end of the section to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(i) * * *

(2) For which no 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 type of devices being compared and a citation to the information upon which the summary is based (class III summary). * * *

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

* * * * *

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0281)

4. Section 807.92 is amended by revising the introductory text of paragraph (a), paragraphs (a)(3), (a)(4), (a)(5), (a)(6), (b), and by adding new paragraph (d) 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. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

* * * * *

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that 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 legally marketed device identified in paragraph (a)(3) of this section, the 510(k) 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 and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design, material, chemical composition energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information

(1) A brief discussion of the nonclinical tests submitted, referenced or relied on in the premarket notification submission for a determination of substantial equivalence;

(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 or effectiveness data obtained from the testing, 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 as safe as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

* * * * *

(d) Any other information reasonably deemed necessary by the agency

5. Section 807.93 is revised to read as follows:

§ 807.93 Content and format of a 510(k) statement.

(a)(1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification

preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(2) The statement in paragraph (a)(1) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as "510(k) statement."

(b) All requests for information included in paragraph (a) of this section shall be made in writing to the certifier, whose name will be published by FDA on the list of premarket notification submissions for which substantial equivalence determinations have been made.

(c) The information provided to requestors will be a duplicate of the premarket notification submission, including any adverse information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in § 20.61 of this chapter.

6. Section 807.94 is revised to read as follows:

§ 807.94 Format of a class III certification.

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

I certify, in my capacity as (position held in company), of (company name), that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the (type of device). I further certify that I am aware of the types of problems to which the (type of device) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the (type of device) is complete and accurate.

(b) The statement in paragraph (a) of this section should be signed by the certifier, clearly identified as "class III certification," and included at the beginning of the section of the premarket notification submission that sets forth the class III summary.

7. Section 807.95 is amended by revising paragraph (d) to read as follows:

§ 807.95 Confidentiality of information.

* * * * *

(d) FDA will make a 510(k) summary of the safety and effectiveness data available to the public within 30 days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a 510(k) submitter has complied with the conditions set forth in paragraphs (b) and (c) of this section, confidentiality for a premarket notification submission cannot be granted beyond 30 days after FDA issues a determination of equivalency.

* * * * *

Dated: November 30, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–30422 Filed 12–13–94; 8:45 am]

BILLING CODE 4160–01–P

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

[Rulemaking No. 110]

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Interim final rule with request for comment.

SUMMARY: The Agency hereby publishes interim final rules governing its oversight and administration of au pair programs. Au pair programs permit foreign nationals to enter the United States for a period of one year for the purpose of residing with an American host family while participating directly in the home life of the family and providing limited child care services. The foreign national also attends a United States accredited post-secondary educational institution. These rules are promulgated pursuant to Public Law 103–415 which authorizes the continued operation, until September 30, 1995, of au pair programs currently designated by the Agency.

DATES: These rules are effective February 15, 1995. With the exceptions of § 514.31(j) (1) and (4), and § 514.31(k) these rules apply to all au pair placements and operations as of February 15, 1995. The provisions set forth at § 514.31(j) (1) and (4) and § 514.31(k) shall apply only to au pair participants placed after February 15, 1995. Written comments regarding this rule will be accepted until January 13, 1995.

ADDRESSES: Comments regarding this rule must be presented in duplicate and addressed as follows: United States Information Agency, Office of the General Counsel, Rulemaking 110, 301, 4th Street, SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Assistant General Counsel, United States Information Agency, 301 4th Street SW., Washington, DC 20547; Telephone, (202) 619–6829.

SUPPLEMENTARY INFORMATION: In January and April of 1986, USIA designated, on a temporary basis, two organizations to carry out au pair programs. These programs were to operate as pilot programs and were governed by rather non-specific program guidelines developed contemporaneously with the temporary designation. At the expiration of this two-year "trial" period, an Agency determination was made not to permanently designate these pilot programs. The decision not to grant permanent designation was based upon a determination that the programs were outside the Agency's statutory authority to oversee educational and cultural exchange activities.

As a result of the Agency's decision not to permanently designate, representatives of these programs approached the Congress and secured special legislation that obligated USIA to continue to implement their au pair programs. This legislative directive was set forth in Public Law 100–461 which also directed the General Accounting Office (GAO) to examine the use of the J-visa in all exchange programs and to report their findings. In light of this legislation and Congressional views, the Agency designated six additional organizations, or "sponsors," to also conduct au pair programs.

The GAO report, issued in February 1990 and entitled, "Inappropriate Uses of the J–Visa," determined that au pair programs, as configured, were not consistent with the Agency's underlying organic authorities as set forth in the Mutual Educational and Cultural Exchange Act of 1961 (Fulbright-Hays Act). In response to this report, the Agency again advised the now eight au pair sponsors, that their au pair programs did not fall within the statutory parameters of the Fulbright-Hays Act. In light of the GAO Report findings, the Agency also sought legislation to transfer the au pair programs to another U.S. Government agency. Agency efforts to transfer au pair programs to another agency were not entirely successful. Pursuant to Public Law 101–454, the Congress directed that USIA continue to implement the eight designated au pair programs, under the same terms and conditions, until the programs, could be