Correction

In the notice of proposed rulemaking FR Doc. 99–30445, beginning on page 67971 in the issue of December 3, 1999, make the following correction in the Addresses section. On page 67972 in the first column, add at end of the first sentence (after the ZIP code) the following: '', or by e-mail to the following address: commentonbaauc@doleta.gov.''

Dated: December 15, 1999.

Raymond L. Bramucci,

Assistant Secretary of Labor.

[FR Doc. 99–32987 Filed 12–20–99 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 99N–4784]

Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its premarket notification regulations to require applicants to submit a redacted version of each premarket notification submission for which FDA has issued an order declaring a device to be substantially equivalent to a legally marketed predicate device. The purpose of this requirement is to provide applicants improved opportunity to protect nonpublic information contained in their premarket notifications while facilitating the release of information to which the public is entitled under the Federal Food, Drug, and Cosmetic Act (the act); the Freedom of Information Act; and FDA's Public Information regulations. The proposed rule does not require submission of a redacted version of any premarket notification received by FDA prior to the effective date of the regulation.

DATES: Submit written comments by March 22, 2000. Submit written comments on the information collection requirements by January 20, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Regulations Staff (HFZ–215), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

Under the act, 21 U.S.C. 301 *et seq.*, FDA clears medical devices for commercial distribution in the United States through three regulatory processes: Premarket approval (PMA), product development protocol (PDP), and premarket notification (a premarket notification is generally referred to as a ''510(k)'' after the section of the act where the requirement is found). In addition, a significant number of devices have been exempted, subject to the limitations on exemptions, from any requirement to obtain premarket notification clearance because FDA has determined that the remaining general controls and special controls are adequate to provide a reasonable assurance of the safety and effectiveness of those devices. A variety of general controls, such as good manufacturing practices (GMP's), establishment registration and device listing, and Medical Device Reporting (problem reporting), and special controls for class II devices, are applicable to devices exempted from premarket notification to control the risks presented by these devices. For additional information on exemption from premarket notification, see 21 CFR 807.85 and FDA's medical device classification regulations, 21 CFR parts 862 through 892.

A. Premarket Notification

Of the three regulatory processes used by FDA to clear medical devices for commercial distribution, the premarket notification or 510(k) process is the most commonly used. The following table 1 summarizes FDA's experience during fiscal year (FY) 1998:

TABLE 1.—PRODUCT APPLICATIONS PROCESSED DURING FY 1998

Responsible center	Premarket Notifications		Premarket Approval Applications		Product Development Protocols		
	Received	Clear	Received	Approved	Received	Approved[1]	Complete
CBER	33	44	2	0	0	0	0
CDRH	4,623	3,824	55	46	11	4	0
All FDA	4,656	3,868	57	46	11	4	0

[1] Approval of a PDP protocol does not constitute marketing approval. A Notice of Completion must be submitted and approved before a device may be marketed under a PDP.

The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally-marketed predicate device. A predicate device can be any of the following: A device legally marketed prior to May 28, 1976 (the date the Medical Device Amendments of 1976 and its premarket notification requirement became law); a device which has been reclassified from class III into class I or class II (the act provides three classes of devices: Class I devices are regulated primarily through general controls, such as registration, listing, and GMP's; class II devices are subject to both general controls and special controls, such as performance standards; class III devices are subject to general and special controls and must also undergo premarket review and approval); or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

Under section 513(i) of the act (21 U.S.C. 360c), a device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or has different characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not

raise different issues of safety or efficacy. A device that is not shown to be substantially equivalent to a predicate device can be marketed only after the sponsor submits, and obtains FDA approval of, a PMA or notice of completion of a PDP, unless the device is reclassified into class I or class II under section 513(e) or section 513(f) of the act.

B. Statutory and Regulatory Requirements Relating to Release of Information in a 510(k)

Certain information in a 510(k) that has been cleared by FDA (i.e., found to be substantially equivalent to a legally-marketed predicate device) is subject to public disclosure under section 513(i)(3) of the act. That section and FDA's implementing regulations require applicants to provide FDA with an adequate summary (510(k) summary) of any information in their submission regarding safety and effectiveness for disclosure by FDA upon request, or alternatively, to submit a statement (510(k) statement) to FDA promising that they themselves will make certain 510(k) information available to the public upon request.

A second Federal statute relevant to the release of 510(k) information is the Freedom of Information Act (FOIA), 5 U.S.C. 552. The FOIA generally makes available for public disclosure all records in an agency's files, whether created by or submitted to the agency, except to the extent those records are covered by one or more of the nine exemptions enumerated in the statute (5 U.S.C. 552(b)). In particular, exemption 4 of FOIA protects from mandatory disclosure trade secrets and confidential commercial information (5 U.S.C. 552(b)(4)). In addition, the act requires withholding of trade secret information from the public, 21 U.S.C. 331(j), and the Trade Secrets Act also prohibits disclosure of trade secrets and confidential commercial information unless specifically authorized by law, 18 U.S.C. 1905. Accordingly, when FDA receives FOIA requests for 510(k) records (other than 510(k) summaries, which are intended for public disclosure as submitted by the applicant) trade secret and confidential commercial information will ordinarily be redacted (i.e., deleted) before the materials are released to the public. Prior to making final decisions about redactions and releasing these records to the public, FDA currently solicits the 510(k) holders' views on what information in their 510(k) submissions may be released to the public and what information may properly be withheld as exempt under FOIA. This practice is consistent with Executive Order 12600, which required agencies to establish predisclosure notification procedures under FOIA to protect confidential commercial information in the agencies' files.

In addition to FOIA's exemption from disclosure for trade secrets and confidential commercial information, FOIA permits the Government to withhold information about individuals in personnel, medical, and similar files, when the disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). With regard to 510(k)s, the issue of personal privacy protection occasionally arises when medical records or other data with patient identifiers are included or summarized in a 510(k). FDA's regulations implementing FOIA request applicants to delete names or other information that could identify patients or research subjects prior to submitting records to FDA, and require FDA to delete such information from any records it discloses (21 CFR 20.63). Similarly, FDA's regulations relating to 510(k)s require those 510(k) holders who submitted a 510(k) statement to FDA to delete such information before releasing a 510(k) (§ 807.93(c) (21 CFR 807.93(c))). (Submission of a 510(k) statement obligates the firm to provide a copy of an appropriately-redacted 510(k) to any requestor.)

Except for information that is exempt from disclosure under FOIA, all information in a 510(k) submission is available for disclosure to the public once the 510(k) is cleared. This includes the original submission, correspondence with FDA, memoranda of telephone conversations, amendments, or other supplemental information submitted prior to clearance of the 510(k) by FDA.

C. Predisclosure Notification and Other Issues Relating to FOIA Requests for 510(k)s

When a request is received for a particular 510(k) that has not been previously released under FOIA, FDA provides the 510(k) holder with a ''predisclosure notification'' in accordance with Executive Order 12600. Subject to certain exceptions, Executive Order 12600 requires the Government to notify submitters of records containing confidential commercial information prior to disclosure of those records in response to a FOIA request. The submitter is then permitted an opportunity to object to the disclosure of any part of the records and to state the basis for each such objection. FDA's predisclosure notification procedures implementing Executive Order 12600 are set forth at § 20.61(d) through (f) (21 CFR 20.61(d) through (f)).

It has been FDA's experience that many 510(k) holders who are provided predisclosure notification by the agency fail to respond adequately; they may not provide an appropriately redacted 510(k), not offer reasons to support redactions, or not respond at all. One reason for this occurrence is that, given the tight statutory timeframes FDA faces for responding to FOIA requests, the 510(k) holder can only be given a very short time to respond to the predisclosure notification; § 20.61(e)(2) requires a response in 5 working days. A second reason is that by the time a FOIA request is filed and predisclosure notification is given, a significant period of time may have passed since the 510(k) was cleared by FDA. As a result, the team of experts at the submitter company that contributed to the development of the 510(k) submission may not be readily available to respond to the predisclosure notification and will, in any case, have to spend time reviewing the 510(k) to refresh recollections and identify trade secrets or confidential commercial information that may be protected from public disclosure.

In addition, because there is no requirement at present for a 510(k) holder to inform FDA when ownership of the 510(k) is transferred to a new party, FDA has, in many instances, been unable to locate and verify the current 510(k) holder for purposes of sending predisclosure notification. Many other 510(k) holders simply fail to respond at all to FDA's predisclosure notification. Consequently, FDA assumed the job of unilaterally redacting many 510(k)s when responding to FOIA requests for those records. As FDA has invested more time and effort in redacting 510(k)s, the resources devoted to responding to 510(k) FOIA requests has inevitably increased. At times, this has resulted in significant backlogs that have delayed the release of information to the public and diverted limited agency resources from other responsibilities, including support for premarket review and postmarket surveillance.

II. Procedural Amendments

The proposed rule would amend § 807.87 (21 CFR 807.87) to require 510(k) applicants to include a statement that would commit the applicant to provide a redacted version of the 510(k) within 30 days of FDA's finding the device substantially equivalent. Proposed § 807.91 sets forth the statement that must be submitted. The statement is referred to as a

''commitment to submit a redacted 510(k).'' The redacted version is one that can be immediately released in response to a freedom of information request, published on the Internet, or otherwise made available to the public. The redacted version would include all sections of the 510(k) submission, including amendments, supplements, and all other documents included in the 510(k) submission, except to the extent that information may be appropriately redacted that is exempt from disclosure under FOIA, such as trade secrets, confidential commercial information, and personal privacy information.

The requirement to provide the redacted version within 30 days of FDA's decision is consistent with the statutory time set by section 513(i) of the act for submission of a 510(k) summary or statement. Although FOIA requires FDA to respond to FOIA requests within 20 days, FDA believes it is unlikely that there will be a real conflict between these two timeframes. This is because FDA publishes a list of 510(k) clearances about the same time each month, resulting in a lag time of at least 5 days, and up to 35 days, between the time of FDA's decision and the announcement of the decision. Although a 510(k) submitter may disclose the clearance of a 510(k) before FDA does, FDA believes it is extremely unlikely that the clearance would be made known and a FOIA request submitted so rapidly that the FDA response would be delayed due to the 30 days applicants would be permitted to provide a redacted version of the 510(k) to FDA.

Applicants would be permitted to use either of two techniques to redact information: (1) The entire 510(k) may be resubmitted with the information to be withheld from disclosure physically obscured to render it unintelligible (e.g., by covering the text or figure with black ink), or (2) the information to be withheld may be omitted from the redacted version, but the extent of each deletion must be described at the place in the document where the redaction was made (e.g., an indication that ''pages 12 through 15 have been redacted'' or ''paragraph concerning sources of raw materials has been deleted''). Simply providing FDA with written instructions such as, ''please do not release Section IV,'' and then expecting FDA to follow those instructions to locate and redact the information as specified by the applicant would be insufficient to comply with the requirement to submit a 510(k) already redacted of information that is exempt from disclosure to the public.

FDA encourages, but would not require, the redacted version to be submitted on disk, preferably as a portable document format file (.pdf file). Submission of .pdf files will facilitate FDA's release of information in electronic form, thereby assisting FDA in complying with its new obligations under the Electronic Freedom of Information Act Amendments of 1996 (EFOIAA) to make reasonable efforts to furnish records in an electronic format when requested to do so.

The proposed rule does not address the redaction of 510(k)s submitted to FDA prior to the effective date of the regulation. FDA will continue to provide predisclosure notification for those documents under the existing approach for the 10 years following their date of submission to the agency (Executive Order 12600 requires predisclosure notification for 10 years following submission of a document), and will address redaction of these 510(k)s on a case-by-case basis using FDA's current approach. Eighty percent of recent FOIA requests for 510(k)s have been for files less than 2 years old. Consequently, the agency expects most of its current predisclosure notification workload to be significantly reduced over time.

The requirement to provide a redacted 510(k) within 30 days of FDA's clearance is expected to provide 510(k) applicants and holders two significant benefits:

First, this approach would permit applicants to consider and address FOIA disclosure issues during and immediately following the development and assembly of the 510(k), while the expert team that contributed to the development of the 510(k) is available and engaged. FDA believes it will be significantly easier and less expensive for the applicant to deal with FOIA disclosure issues at an early stage rather than having to reassemble experts to review the 510(k) and resolve disclosure issues at some indeterminate time in the future.

Second, FDA believes this approach would permit applicants to have a larger voice in determining what information would be protected from disclosure. Indeed, this approach recognizes that the firm is in a uniquely well-qualified position to identify trade secret and confidential commercial information relating to its own 510(k) submission. Currently, FDA assumes the entire responsibility for designating what information is considered trade secret or other confidential information in a 510(k) when it cannot locate the current owner of the 510(k) or when the owner fails to respond to predisclosure notification within an appropriate time. Because FDA is unlikely to have all the information that would be available to the submitter, FDA may not identify trade secret and confidential commercial information in the 510(k) in the same way as the 510(k) holder would have done.

In addition to these two direct benefits, device applicants would also benefit indirectly from the approach set forth in the proposed rule because FDA would be able to free some resources it currently spends on efforts to determine what information should be protected from disclosure. Therefore the focus would be on those resources instead on activities more directly related to the device review process.

The proposed rule would benefit FDA in two key ways:

1. It would eliminate the need to routinely provide individual predisclosure notification to 510(k) holders when a 510(k) is requested under FOIA; currently, 510(k) submissions are the only significant category of records maintained by FDA that requires predisclosure notification. Given the significant volume of FOIA requests for 510(k)s and the time and effort required to process them under the current system, adopting the approach established by the proposed rule would significantly improve FDA's ability to provide timely responses to FOIA requests for 510(k)s and at the same time would allow the agency to redirect resources to product reviews and other activities more closely related to the agency's public health mission.

2. As discussed above, the regulation would ensure that the party that is in the best position to identify trade secret and confidential commercial information assumes primary responsibility for redacting that information.

The proposed rule will benefit the public by making information to which the public is entitled available in a more timely manner and at lower cost.

A. Copyrighted Information Provided in a 510(k)

Submitters of 510(k)s occasionally provide copyrighted materials to FDA in support of their submissions. When a FOIA request is received for a 510(k) that includes copyrighted materials, FDA may include a copy of any of those materials in response to the request, except to the extent that such materials are exempt under FOIA exemption four. FDA's disclosure of nonexempt information contained in copyrighted materials in response to a FOIA request is generally considered a ''fair use under the Copyright Act of 1976 (17 U.S.C. 101

et seq.) and, thus, does not constitute copyright infringement. See 17 U.S.C. 107, and Office of Information and Privacy, U.S. Department of Justice, Copyrighted Materials and the FOIA, *FOIA Update*, Fall 1983, at pp. 3 to 5.

The EFOIAA amend FOIA to require Federal agencies to make certain FOIA responses available to the public ''by computer telecommunications or *** other electronic means,'' such as posting the FOIA response on the Internet. The Department of Justice has advised Federal agencies that when records are made available through electronic means such as the Internet, the agency ''should guard against the possibility that such extraordinarily wide dissemination of the record *** might be regarded as copyright infringement.'' See U.S. Department of Justice, *Amendment Implementation Questions*, *FOIA Update*, Winter 1997, at pp. 3 to 4.

FDA intends to make all redacted 510(k)s available through the Internet, regardless of whether a FOIA request has been received. This will make the information in those 510(k)s available to the public more rapidly and without having to pay fees which may be assessed when FDA responds to a FOIA request. FDA recognizes the need to avoid infringing copyrights when providing redacted 510(k)s through the Internet, and believes that it can provide appropriate protection of copyrighted materials by distinguishing between two categories of materials: Those whose copyright is owned by the applicant (e.g., an operating manual for a device) and those whose copyright is owned by another person (e.g., a copy of an article from a medical journal).

Under the proposed rule, copyrighted materials whose copyright is owned by a person other than the applicant must be placed in a single appendix, as required by proposed § 807.90(e), and listed in a bibliography, as required by proposed § 807.87(k). These copyrighted materials may not be included in any other portion of the 510(k). They may be referred to at any point in the 510(k) by citing the appropriate entry in the bibliography of copyrighted materials. FDA will not release the appendix containing copyrighted materials as part of a redacted 510(k) made available through FDA's Internet site, but would release the bibliography of materials included in the appendix.

Copyrighted materials whose copyright is owned by the applicant may be included, at the applicant's discretion, in any portion of a 510(k). FDA would treat these materials in the same manner as any other information submitted in a 510(k) and would include them in any redacted 510(k) made available through FDA's Internet site. FDA also intends to include a warning concerning the need to respect copyrights with all copyrighted materials the agency provides through the Internet. An applicant who is concerned about possible copyright infringement by persons who obtain a redacted 510(k) from FDA's web site may wish to clearly indicate when included material is copyrighted or reformat the information prior to submitting a 510(k) to avoid submitting copyrighted materials.

FDA recognizes that there is some uncertainty concerning the most appropriate method of protecting copyrighted materials included in a 510(k). For that reason, FDA is requesting comments on both the approach set forth in the proposed rule and on alternative approaches. Possible alternatives include, but are not limited to, the following:

FDA could permit copyrighted materials from any source to be included anywhere in the 510(k) and could include those materials with the redacted 510(k) made available through the agency's Internet site, while providing a clear and prominent warning to persons who download the redacted 510(k) that they must avoid infringing copyrights and may not make use of any copyrighted material unless such use would be a ''fair use.''

FDA could require explicit consent from each copyright holder, permitting FDA to release those copyrighted materials through the agency's Internet site as part of the redacted version of the 510(k). An applicant would not be permitted to submit copyrighted material without providing the required consent. If a copyright holder refuses to provide the required consent, the applicant would be required to reformat or summarize the relevant information from copyrighted materials prior to submitting the 510(k) for clearance.

FDA could prohibit the inclusion of any copyrighted materials whose copyright is owned by the applicant or by any person who prepared the materials at the request of the applicant unless the applicant or its agent consents to release of the material on FDA's Internet site. Applicants who did not provide the required consent would have to reformat the information to avoid the need to submit the copyrighted material. Applicants would be permitted to submit copyrighted materials from medical journals and other independent sources by including them in a separate appendix and listing them in a bibliography.

FDA has also requested that the Department of Justice provide its opinion concerning FDA's proposed approach. FDA will consider the Department of Justice's response and any comments received on FDA's proposed approach and alternative approaches in preparing a final rule.

B. Implementation and Enforcement

Under the proposed rule, FDA would not routinely review each redacted 510(k) to ensure that the applicant has redacted all confidential commercial information potentially eligible for protection. In addition, except for cases of clearly abusive redactions (e.g., a claim by a submitter that an entire file is exempt from disclosure), FDA will rely on parties that request a 510(k) (through FOIA or other channels) to raise any issue of excessive redaction. If FDA learns that an applicant has inappropriately redacted information not eligible for protection from disclosure under FOIA, FDA may require the applicant to resubmit an appropriately redacted version, or may release the inappropriately redacted information and pursue enforcement action. This approach will enable FDA to provide information more rapidly and focus more of its resources on device review.

FDA retains exclusive authority to make final determinations concerning whether a redaction is permitted under FOIA and is not delegating this authority to any person required to submit a redacted 510(k). Failure to provide a redacted version of a 510(k) in accordance with a commitment to submit a redacted 510(k) made under § 807.87(j) would be a prohibited act under sections 301(p) and (q) of the act (failure to provide any information required by section 510(k) and failure or refusal to furnish information required under section 519 of the act, records and reports on devices), 21 U.S.C. 331(p) and (q), and may result in FDA enforcement action, including administrative civil money penalties of up to $15,000 per violation (21 U.S.C. 333(f)). Some of the resources currently devoted to identifying what information should be protected from disclosure could be redirected, when necessary, to compliance actions against submitters who do not follow the new rule.

C. Relation to Requirement for a 510(k) Summary or 510(k) Statement

Section 513(i)(3) of the act requires a 510(k) applicant to include an adequate summary of any information respecting safety and effectiveness (''510(k) summary'') with each 510(k) submission or to state that such information will be

made available upon request of any person (''510(k) statement''). Applicants who choose to include a 510(k) statement in lieu of a 510(k) summary must respond to written requests by an individual for a copy of the 510(k), excluding patient identifiers and trade secret and confidential commercial information, within 30 days of receipt of the request. The information to be made available to a requestor is ''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'' (21 CFR 807.3(o)). Holders of 510(k)s may not charge requestors for compiling and providing this information. Noncompliance with the 510(k) statement is a prohibited act under section 301(p) of the act.

The information which a 510(k) submitter must provide to requestors when it elects to submit a 510(k) statement is the same information that would be required to be submitted to FDA under this proposed regulation, that is, a redacted 510(k). To avoid imposing redundant burdens on 510(k) submitters, FDA will, at the submitter's option, assume the burden of responding to requests for safety and effectiveness information made under section 513(i) of the act. Submitters who have submitted an appropriately redacted 510(k) to FDA will be permitted under proposed § 807.93(d) to refer all such requests to FDA's Internet site (at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/search.cfm). Assuming the submitter has provided an appropriately redacted 510(k) that meets FDA's requirements, all the 510(k) submitter will be required to do to fulfill its statutory obligation is to inform the requestor that the requested information is available on FDA's Internet site; this response to the requestor would have to be made within 10 days of the request. FDA believes this approach will reduce costs submitters now accrue when they submit a 510(k) statement and that requestors will find it easier to obtain all such information from a single source.

A submitter who wishes to submit a 510(k) summary instead of a 510(k) statement will still be permitted to do so, but submission of a 510(k) summary will not relieve the submitter of its obligation under this proposed rule to submit a redacted 510(k) to FDA. Section 807.93(a) has been amended to provide alternative 510(k) statements. Section 807.93(a)(i) provides the statement to be submitted by a firm that chooses to continue to reply directly to requests for safety and effectiveness information; proposed § 807.93(a)(ii) provides the statement to be submitted by a firm that chooses to have FDA respond on the firm's behalf to such requests.

A person who previously submitted a 510(k) statement, and thereby committed to make available a redacted copy of the 510(k) upon the request of any person, may revoke that statement by submitting a redacted 510(k) to FDA. FDA will then assume the responsibility for responding to requests for the redacted copy on behalf of that person. Submitting a redacted 510(k) to FDA permits persons who have found it burdensome to respond to such requests an opportunity to shift the responsibility to FDA.

III. Request for Comments

Interested persons may, on or before March 22, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Comments regarding the information collection provisions should be submitted by January 20, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Environmental Impact

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

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). The Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. The proposed rule is limited to minimize its impact in two significant ways: (1) There is no retrospective effect, because the regulation will not apply to premarket notifications received by FDA prior to the effective date of the regulation, and (2) it will not apply to premarket notifications that were not found substantially equivalent or which were withdrawn. FDA believes there will be no long-term impact on most persons whose premarket notifications are found substantially equivalent because the primary effect of the regulation will affect only the timing of when a redacted version will be required.

FDA currently bears the burden of redacting 35 percent of premarket notifications requested under FOIA without any input from the applicant, either because the applicant cannot be located or does not respond to predisclosure notification. Therefore, this rule is expected to shift to a great extent the resources needed to redact submissions from FDA to the applicant who is in a much better position to redact the 510(k). FDA estimates that 1,240 submissions are affected and that for each submission it will take manufacturers 2 hours to comply. In addition, submitters of the 4,423 premarket notifications that are found substantially equivalent will spend up to 15 minutes to prepare and submit a statement of compliance with this rule to FDA. Using hourly earnings of $35, FDA estimates the total annual cost of compliance with this proposed rule is approximately $125,500. The hourly earnings are derived from the Statistical Abstract of the United States 1997, Table 672 median annual earnings in 1995 for men in a professional specialty, adjusted for fringe benefits and pay increases (30 percent and 20 percent, respectively). Because these costs are based on no more than 2.25 hours per submission and are spread over many submitters, this rule will not have a significant economic impact on small entities.

FDA further believes that by preparing the redacted version earlier, while the expert team that contributed

to the development of the 510(k) is available and engaged, there may be some long-term savings when compared with the costs of delayed redaction inherent in the current approach.

This rule is not a significant regulatory action as defined by the Executive Order, and is not subject to review under the Executive Order. This rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Furthermore, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions 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 each collection of information.

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

Title: Addition of Written Commitment to Submit, and Submission of, a Redacted Premarket Notification upon FDA's Finding of Substantial Equivalency

Description: The statutory authority for this proposed regulation includes: (1) The authority to require premarket notification (generally referred to as 510(k)) (21 U.S.C. 360(k)); (2) The Freedom of Information Act (5 U.S.C. 552) (FOIA) because a premarket notification that has been cleared by FDA (found to be substantially equivalent) is subject to public disclosure under 5 U.S.C. 552, which requires Federal agencies to release all agency records, including materials obtained by the agency, except to the extent a FOIA exemption applies; (3) FOIA sections 552(b) and (c), and specifically 552(b)(4), permit withholding of certain information from public disclosure, including ''trade secrets and commercial or financial information obtained from a person and privileged or confidential;'' and (4) section 513(i)(3) of the act requires an adequate summary of information respecting safety and effectiveness to be provided by the submitter of a 510(k) that has been cleared by FDA. In addition, the act requires withholding of trade secret information from the public (21 U.S.C. 331(j)), and the Trade Secrets Act also prohibits disclosure of trade secrets and confidential commercial information unless specifically authorized by law, 18 U.S.C. 1905.

These proposed reporting requirements are intended to provide applicants with an improved opportunity to protect nonpublic information contained in their premarket notifications while facilitating the release of information to which the public is entitled. The proposed rule would preserve scarce FDA resources because it proposes to eliminate the need for FDA to routinely redact any 510(k) submitted after the effective date except to the extent challenges are raised to the redactions made by the applicant or in other cases where the agency finds that the applicant has not provided an appropriately redacted 510(k). The proposed rule also would preserve FDA resources by eliminating the need to routinely provide individual predisclosure notification and followup to 510(k) holders when a 510(k) is requested. The proposed written commitment to submit a redacted 510(k) is intended to provide FDA with assurance that the applicant agrees to provide the redacted 510(k) within 30 days of FDA issuing its substantial equivalence order.

The proposed rule would require the premarket submission to include a written commitment from the submitter agreeing to provide a redacted version of their 510(k) (from which those portions that contain ''trade secrets and commercial or financial information obtained from a person and privileged or confidential or protected personal privacy information'' are deleted) within 30 days of FDA issuing its order of substantial equivalence, together with a redacted copy of the 510(k).

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.87(j) and 807.91	4,423	1	4,423	0.25	1,106
807.95(f)	3,675	1	3,675	2.00	7,350
Total Hours				2.25	8,456

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

Several steps were performed by FDA to derive the burden hour estimates. FDA estimated the number of respondents by first taking the number of 510(k)s filed and cleared during FY 1998 (4,656) and reducing those numbers by roughly 5 percent because the number of 510(k)s filed in the past few years has been decreasing at approximately that rate (6,434 510(k)s were received during FY 94, compared with 4,656 during FY 98; 510(k) receipts have decreased each year since FY 94). The projected number of 510(k)s filed provides the number of respondents (approximately 4,423) affected by proposed § 807.87(j).

To determine the number of respondents affected by proposed § 807.95(f), FDA estimated the number of 510(k)s expected to be cleared (approximately 3,675), using the methodology previously described.

FDA then estimated the amount of hours per response. The estimate for proposed § 807.87(j) is based on FDA's professional judgment. The estimate for proposed § 807.95(f) is based on FDA's direct experience in redacting 510(k)s. FDA then multiplied the total annual responses by the hours per response to obtain the total hours. The hours per response includes the amount of time to add the statement to the premarket submission and to review and redact the premarket submission. There are no capital or operating and maintenance costs associated with this information collection.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), FDA has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 20, 2000, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

List of Subjects in 21 CFR Part 807

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

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

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

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

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

2. Section 807.87 is amended by redesignating paragraphs (j), (k), and (l), as paragraphs (l), (m), and (n); and by adding new paragraphs (j) and (k) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(j) A written commitment, as described in § 807.91 that the submitter will provide to FDA, no later than 30 days after the date of the FDA order declaring the device to be substantially equivalent under § 807.100(a)(1), a copy of the premarket notification submission, with all information that is exempt from public disclosure in accordance with part 20 of this chapter redacted in accordance with § 807.95(f).

(k) A bibliography of all copyrighted materials included in the premarket notification submission.

* * * * *

3. Section 807.90 is amended by adding paragraph (f) to read as follows:

§ 807.90 Format of a premarket notification submission.

* * * * *

(f) Include any copies of copyrighted materials in a single appendix, which shall be the final section of the premarket notification. Copyrighted materials whose copyright is not owned by the applicant shall not be included in any other section of the premarket notification.

4. Section 807.91 is added to subpart E to read as follows:

§ 807.91 Commitment to submit a redacted 510(k).

(a) A statement committing to submit a redacted 510(k) 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 submit to FDA, no later than 30 days after the date of an FDA order under § 807.100(a)(1) declaring this device to be substantially equivalent, a redacted copy of the entire premarket notification as required by § 807.95(f).

(b) The statement in paragraph (a) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as ''Commitment to Submit a Redacted 510(k).''

5. Section 807.93 is amended by revising paragraph (a) and by adding paragraphs (d) and (e) 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 (choose one):

(i) Option 1—For firms that will directly respond to all requests for information:

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 § 20.61.

(ii) Option 2—For firms that choose to have FDA respond on the firm's behalf to all requests for information:

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 refer all requests for information included in this premarket notification to FDA's Internet site (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/search.cfm) within 10 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent.

(2) The statement in paragraph (a)(1)(i) 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.''

(3) The statement in paragraph (a)(1)(ii) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as ''Commitment to Refer 510(k) Requests to FDA.''

* * * * *

(d) At the option of a 510(k) submitter who has elected to submit the statement provided in paragraph (a)(1)(ii) of this section and who has submitted an appropriately redacted 510(k) to FDA under § 807.95(f), all requests received by the submitter for information included in paragraph (a) of this section may be satisfied by referring the requestor to FDA's Internet cite.

(e) A previously submitted 510(k) statement may be revoked any time, subject to the following requirements:

(1) A revocation of a 510(k) statement is made by submitting a copy of all information submitted with, or incorporated by reference in, the premarket submission, from which information that is exempt from public disclosure under part 20 of this chapter has been redacted.

(2) Redactions shall be made as specified by § 807.95(f).

(3) The redacted copy is to be sent to FDA's Center that reviewed the 510(k) at the appropriate address provided in § 807.95(f)(4).

(4) A revocation of a 510(k) statement becomes effective 30 days after it has been submitted to FDA. The submitter must respond to all requests for information received prior to the effective date.

6. Section 807.95 is amended by adding paragraph (f) to read as follows:

§ 807.95 Confidentiality of information.

* * * * *

(f)(1) Not later than 30 days after the date of the FDA order issued under § 807.100(a)(1) declaring a device to be

substantially equivalent, the submitter shall send to FDA a copy of all information submitted with, or incorporated by reference in, a premarket submission, from which information that is exempt from public disclosure under part 20 of this chapter has been redacted in one of the following two ways:

(i) The information exempt from disclosure has been physically obscured so as to render it illegible, e.g., by covering the text or figure with black ink.

(ii) The information exempt from disclosure has been omitted. In such cases, the extent of the deletions shall be described, e.g., ''Pages 12 through 15 have been deleted.''

(2) Whenever copyrighted materials are obscured or omitted, a reference to the bibliographic entry identifying the material under § 807.87(k) shall be included at the point where the materials originally appeared in the submission.

(3) The redacted copy may be submitted on a disk as a portable document format (.pdf) file.

(4) The redacted copy is to be sent to the center that reviewed the 510(k) at the appropriate address: Food and Drug Administration, Center for Devices and Radiological Health (HFZ–82), 2098 Gaither Rd., Rockville, MD 20850, or Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–99), 11401 Rockville Pike, Rockville, MD 20852.

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–33003 Filed 12–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 655

[FHWA Docket No. FHWA–99–6190]

RIN 2125–AE67

Traffic Control Devices on Federal-Aid and Other Streets and Highways; Color Specifications for Retroreflective Sign and Pavement Marking Materials

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to revise its color specifications for retroreflective signing materials. This revision would include daytime and nighttime specifications for both assigned and unassigned colors found in the Manual on Uniform Traffic Control Devices (MUTCD). Color specifications for fluorescent colors and pavement marking material would also be included.

DATES: Comments must be received on or before June 21, 2000.

ADDRESSES: Signed, written comments should refer to the docket number that appears at the top of this document and must be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Ernest Huckaby, Office of Transportation Operations (202) 366–9064, or Mr. Raymond Cuprill, Office of the Chief Counsel (202) 366–1377, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users may access all comments received by the U.S. Dockets, Room PL–401 by using the universal resource locator (URL): *http://dms.dot.gov.* It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help. An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.*

Background

The MUTCD is incorporated by reference in 23 CFR. The color specifications found in the appendix to subpart F of part 655 of 23 CFR are incorporated by reference in the MUTCD.

The current specifications for the color of retroreflective sign sheeting were determined on the basis of material available more than 15 years ago. Since then, new microprismatic material has been commercially available and the original CIE Illuminant C [1] has been replaced with CIE Illuminant D 65. In addition, an extensive international effort is in progress to specify the nighttime appearance of retroreflective materials. Lastly, expanding the specifications to include fluorescent materials is also necessary at this time. In addition to revising the daytime color specifications for retroreflective sign sheeting material used primarily for traffic signs, color specifications for pavement markings and markers would be added. The first introduction of the color specification for nighttime use of these materials would be included in this revision. Instrumentation for measuring retroreflectivity is now available for in-situ measurements as well as ease in quality control and lab measurements. Color instruments are available for daytime measurements of traffic signs and pavement markings. New pigment formulations, especially for pavement marking material, are now in use because of environmental concerns. The American Traffic Safety Services Association assisted FHWA in soliciting samples for measurement from sign sheeting material and pavement marking material manufacturers. Samples were received from 11 manufacturers. Several types of pavement marking materials were received, *i.e.,* paint, tape, epoxy, and polyester. Polycarbonate and other signing materials were not included in the sampling. Manufacturers of polycarbonate and other material may provide signs that conform to the color limits stated for sign sheeting material.

Definitions

The following discussion on the procedures followed to develop this proposed revision contains abbreviations which are defined as follows:

Material types:

eg = enclosed lens sheeting material
encp = encapsulated lens sheeting material
seg = super-engineering grade material
up = microprismatic sheeting material (or vinyl)
exp = exposed glass spheres for pavement marking materials

Measurement units:

mm = millimeter

[1] Illuminant C is a standard from the International Commission on Illumination (CIE) for filtered tungsten illumination that simulates average daylight with a color temperature of 6,774 degrees K. Illuminant D 65 is a standard representing daylight with a correlated color temperature of 6504 K.