II. Comments

Interested persons may submit either written comments to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

FDA invites comment on all matters relating to a potential program for reserving proprietary names for drug products. This request is not limited to comments on the proposal described in the submission by PhRMA. FDA is particularly interested in comments and information regarding the following:

- Are there examples of drug market launches being delayed, or of drugs being launched without a proprietary name, because FDA's determination that a proposed proprietary name would not be acceptable came too close to the date of product approval? If so, please provide details, including how far in advance of approval the applicant submitted the proposed name to the Agency, whether the proposed name had been tentatively accepted, and how long the launch was delayed or how long the product was marketed without a proprietary name.
- Potential approaches for reserving proprietary names that would create more certainty for applicants than the current ''tentative acceptance'' process. For each proposed approach, please describe the following:
  - How the program would create certainty while balancing the need to avoid or minimize the risk of medication error.
  - The parameters of the proposed program, including whether participation in the program should be voluntary or mandatory; what conditions should be met before a name is ''reserved''; and for how long a name may be ''reserved.''
  - The procedural and legal framework for the proposed program.
  - Whether the ''reservation'' of a proprietary name for one applicant would be binding, such that a similar or identical proprietary name for another applicant's drug would be rejected, even in situations in which such drug is ready for approval before that of the applicant for whom the name is ''reserved.''
  - A discussion of the application of the program to over-the-counter monograph products and drugs that are manufactured for a private label distributor, under an existing approved application.
- Data and information regarding:
  - The number of applicants that would be interested in participating in a voluntary name reservation program.
  - Whether applicants would be willing to participate voluntarily if ''reservation'' of a name is not guaranteed to prevent the use of the name by all other drugs that enter the U.S. market prior to the drug for which the name is ''reserved.''
- In the absence of a binding name reservation program, what measures could be used to provide greater predictability to applicants about the likelihood that a name found tentatively acceptable will subsequently be approved? Can industry address this without FDA involvement, for example, through a voluntary posting of proposed names?
- Under current FDA regulations, information in an unapproved application, including proposed proprietary names, is generally not publicly available (*see* 21 CFR 312.130, 314.430, 601.50 & 601.51). What mechanisms could be used to provide notice to an applicant of possible confusion between its proposed proprietary name and other proposed proprietary names contained in pending applications?

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17691 Filed 7–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0652]

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].'' This guidance document describes FDA's current review practices for premarket notification (510(k)) submissions by describing in greater detail the regulatory framework, policies, and practices underlying FDA's review of traditional 510(k) submissions. This guidance document does not address the special and abbreviated 510(k) programs. FDA intends to finalize those sections separately.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marjorie Shulman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1536, Silver Spring, MD 20993–0002, 301–796–6572; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance serves to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence under the 510(k) program. Since the program's inception in 1976, FDA has periodically published documents, including guidance

documents, which describe FDA's approach and any changes therein to the 510(k) program. On June 30, 1986, FDA published a Blue Book Memorandum entitled ''Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum #K86–3'' (the ''#K86–3 Memorandum''). This document discussed general points regarding the process of determining substantial equivalence between a new device and a predicate device. On March 20, 1998, FDA published a guidance document entitled ''The New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications'' (''the New 510(k) Paradigm''). This guidance introduced two new 510(k) programs—the Special 510(k) and the Abbreviated 510(k)—as optional approaches available to device manufacturers and renames the original 510(k) program that had been in place since 1976 to the ''Traditional 510(k).'' Traditional, Special, and Abbreviated 510(k)s differ with respect to the scope and content of information that are included within the submission. It is noted that the #K86–3 Memorandum was issued as a final guidance prior to the February 27, 1997, implementation of FDA's Good Guidance Practices, 21 CFR 10.115. Neither the #K86–3 Memorandum nor the New 510(k) Paradigm has been updated since its initial publication. As further explained later in this section, this new guidance document will replace only the #K86–3 Memorandum.

On December 28, 2011, FDA announced the availability of ''Draft Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' (76 FR 81510) (the ''Draft Guidance''). Interested persons were invited to comment by April 26, 2012. FDA received 26 sets of comments, totaling over 400 comments. While the sections on Special 510(k), technological characteristics, and predicate devices received the most comments, there were also requests for inclusion of examples to assist in defining the gray areas of how FDA interprets what would be considered substantially equivalent under the 510(k) program.

In response to these comments, the guidance was revised to provide a broader overview of the use of predicate devices and to explain more clearly the intent and value of defining a ''primary predicate'' device in the submission. Examples were added to several sections to clarify the boundaries and FDA's decision-making process for finding devices equivalent to a predicate that may have different indications for use, technological characteristics, or performance characteristics. There were requests for the addition of a ''fillable form'' to ensure consistency in the amount and type of detail expected in a 510(k) summary. In response, an appendix was added with a sample 510(k) summary, including clinical data, to demonstrate the level of detail that is expected in each regulatory mandated section upon finalization of the guidance to increase transparency.

Lastly, industry expressed concern relating to the inclusion of the Special 510(k) Program within this guidance, given the connection of this topic and determining when it is necessary to submit a new 510(k) for a device modification. In response, FDA elected to remove the sections addressing the alternatives to Traditional 510(k)s, specifically the Special and Abbreviated 510(k) programs that were included in the draft guidance. FDA intends to finalize these sections separately. Until FDA issues a new final guidance document on the Special and Abbreviated 510(k) Programs, the recommendations for Special and Abbreviated 510(k)s contained in the New 510(k) Paradigm remain in effect for these alternate submission types.

In response to other minor substantive and editorial comments, FDA revised the guidance document to clarify the processes and policies as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1766 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17666 Filed 7–25–14; 8:45 am]

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