framework for such drugs, and criteria for BTC availability.

Specifically, we are seeking input on the following issues related to BTC:

General

1. Should there be BTC availability of certain drug products? If so why? If not why?
2. What might the impact of BTC be on patient access?
3. What might the impact of BTC be on patient compliance with drug therapy?
4. What should the criteria or standards be for a drug to be treated as BTC?
5. Please comment on the following criteria for what roles a pharmacist or other health professional might play, which are included below for discussion purposes. For example, a pharmacist or other practitioner licensed by law to dispense prescription drugs prior to sale might:

(A) Review or conduct an initial screening for clinical laboratory test results, contraindications, or drug interactions;

(B) Counsel the patient on safe use;

(C) Monitor for continued safe or effective use.

6. Should BTC availability be used as a temporary or transitional status for drugs that move from prescription status to OTC versus a permanent status?
7. Should there be criteria or standards for a drug to transition out of BTC status to OTC status? If so, what should these criteria or standards be?
8. If safety concerns arise, should there be criteria or standards for a drug to transition out of BTC status to prescription status? Or from OTC status to BTC status? If so what should these criteria or standards be for each scenario?
9. What effect would BTC availability have on patient access to medications in this category?
10. How could we evaluate whether BTC improves patient access to medications?
11. Would BTC availability be cost-effective to patients? Please explain.
12. What effect would BTC availability have on patient safety?
13. What measures would be necessary to ensure patient safety?
14. In general, what are the benefits and costs to the healthcare system as a whole related to BTC availability?

Logistics

1. Discuss logistical challenges for pharmacy storage and dispensing of BTC drugs. How might these challenges be addressed?
2. What dispensing procedures should be associated with BTC medications?
3. What types of records should be kept in association with BTC dispensing? If such records were to include patient laboratory values, how would the pharmacist gain access to this information as well as other information in the patient's medical records?
4. How would patient privacy be protected in a retail pharmacy setting? Please discuss any privacy concerns that would need to be addressed.
5. Should reimbursement be available to pharmacists for providing services associated with BTC dispensing? What type? What type of billing procedures could be utilized and how would third party companies facilitate such reimbursements?
6. Who would oversee a BTC program? What impact would it have on States and what might be the role for the State boards of pharmacy?
7. Would special training be needed for pharmacists to participate in dispensing BTC medications? If any, what type of training would this entail?
8. Would special training be needed for other pharmacy staff to aid in managing the work flow (storage, record keeping, distribution) and additional BTC responsibilities of the pharmacist(s) and the pharmacy? If so, what type of training or measures should be put in place?
9. Could qualified healthcare professionals/providers other than pharmacists be responsible for dispensing of BTC drugs? If so, what types of healthcare professionals/providers? And in what type of settings could this situation be accommodated?
10. What impact would BTC availability of drugs have on the practice of pharmacy?
11. What impact would BTC availability of drugs have on the practice of medicine?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the docket for the meeting will open 14 days prior to the meeting and remain open for 30 days following the meeting. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by the number and subject to which they refer in the previous text in this document. Please 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. Transcripts of the meeting also will be available for review at the Division of Dockets Management.

Dated: September 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19329 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. [2001D–0193 (formerly 01D–0193)]

Guidance for Industry and Food and Drug Administration Staff; Biological Indicator Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions.'' The agency is issuing this guidance document to provide information that will help manufacturers prepare premarket notification submissions for these devices. The document provides guidance regarding performance characteristics for biological indicator devices, which are intended to monitor the effectiveness of sterilizers used in healthcare facilities.

DATES: Submit written or electronic 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 ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151 or 1–800–638–2041. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sheila Murphey, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3747.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is for biological indicator devices intended for use in health care facilities to monitor the effectiveness of sterilizers. Biological sterilization process indicators are class II devices identified in 21 CFR 880.2800(a). In the **Federal Register** of May 21, 2001 (66 FR 27985), FDA invited interested persons to comment on the draft guidance entitled ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers.''

FDA received five comments on the draft guidance. Many of the comments are addressed by the voluntary consensus standards that have been recognized by FDA since the draft was issued and that are now cited in the guidance. We addressed comments that suggested the statistics in the validation protocol were too restrictive by clarifying that these statistics are examples, not thresholds. We also revised the guidance for clarity and brevity in response to the comments received.

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 ''biological indicator premarket notification submissions.'' 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 using the Internet. To receive ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1320 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

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 USC 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB Control Number 0910–0120. The labeling provisions addressed in the guidance have been approved under OMB Control Number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 26, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–19573 Filed 10–3–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0309]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' The draft guidance describes a means by which the electrocardiograph electrode device may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate this draft guidance as the special control for this device and would exempt the device from premarket notification requirements, subject to specific limitations, if the device addresses the issues identified in the guidance by following its recommendations. The draft guidance document is not final, nor is it being implemented at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 2, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.