CFSR PERMANENCY OUTCOME 1—Continued

Current CFSR data measures and standards associated with CFSR Permanency Outcome 1	Proposed composites to be associated with Permanency Outcome 1
Timeliness of adoption measure and national standard: of all children exiting foster care to a finalized adoption, 32.0 percent or more achieved a finalized adoption within 24 months of the time of entry into foster care.	Permanency Composite 2: Timeliness of adoption. A national standard will be established from the data composite scores resulting from States' performance on the areas incorporated in the composite. Some possible performance areas to be included in the composite are: • Performance area 1: Timeliness of adoptions of children discharged from foster care to a finalized adoption. • Performance area 2: Timeliness of adoptions of children who are in foster care for 17 months or longer at the start of a fiscal year. • Performance area 3: Timeliness of adoptions of children for whom parental rights had been terminated. • Performance area 4: Timeliness of achieving termination of parental rights for children who have been in foster care for 17 months or more at the start of a fiscal year.
Placement stability measure and national standard: of all children in foster care who have been in care for less than 12 months, 86.7 percent or more had no more than 2 placement settings.	Permanency Composite 3: Placement stability. A national standard will be established from the data composite scores resulting from States' performance on the area incorporated in the composite. Some possible performance areas to be included in the composite are: • Performance area 1: Stability of children's placement experience during the first year in foster care. • Performance area 2: Stability of children's placement experience for children in foster care for longer than 12 months.
No national standard measure. Information captured in the case review instrument.	Permanency Composite 4: Achieving Permanency for Children in Foster Care. A national standard will be established from the data composite scores resulting from States' performance on the areas incorporated in the composite. Some possible performance areas to be included in the composite are: • Performance area 1: The extent to which children are growing up in foster care. • Performance area 2: Timeliness of establishing permanency goals. • Performance area 3: The extent to which children with TPR exit foster care to a permanent family.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005G–0367]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' This guidance document has been developed as a special control guidance document to support the classification of the low energy ultrasound wound cleaner into class II (special controls). The device is intended for the cleaning and maintenance debridement of wounds. This guidance document describes a means by which the low energy ultrasound wound cleaner may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the low energy ultrasound wound cleaner into class II (special controls). The guidance document is immediately in effect as the special control for the low energy ultrasound wound cleaner, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

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 on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner'' 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 301–443–8818. 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 *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David B. Berkowitz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 152.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance document ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner'' has been developed as a

special control guidance document to support the classification of the low energy ultrasound wound cleaner into class II (special controls). This device is intended for the cleaning and maintenance debridement of wounds. On April 29, 2004, Celleration, Inc., submitted a petition requesting classification of the Celleration MIST Therapy System™ under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the low energy ultrasound wound cleaner into class II (special controls) under section 513(f)(2) of the act. This guidance document will serve as the special control for the low energy ultrasound wound cleaner device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation in § 10.115. The guidance represents the agency's current thinking on the low energy ultrasound wound cleaner for the cleaning and maintenance debridement of wounds. 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

To receive ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1302 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. 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 contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB 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: October 5, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

Food Safety Inspection Service

[Docket No. 05–013N]

Meeting To Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry

AGENCIES: Food and Drug Administration, HHS; Food Safety Inspection Service, USDA.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in the Department of Health and Human Services, and the Food Safety Inspection Service (FSIS), in the United States Department of Agriculture (USDA), are jointly announcing a public meeting to discuss and solicit information on an approach for providing consistency and predictability with respect to which of the two agencies should have jurisdiction over certain types of food products that contain meat and poultry as ingredients, as well as the opening of a joint agency docket to receive written comments. This notice outlines that approach and solicits comments on it and on the specific questions asked in section II below.

DATES: The public meeting will be held on December 15, 2005, from 10 a.m. to 4 p.m.

ADDRESSES: The public meeting will be held at the Donald E. Stephens Convention Center, 5555 North River Road, Rosemont, IL 60018, 847–692–0222.

You may submit comments, identified with Docket No. 05–013N, by any of the following methods:

- Electronic mail:

FSIS: FSIS *regulationsComments@fsis.usda.gov*. Follow the instructions for submitting comments on the Agency's Web site.