DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006F–0058]

ARCH Chemicals, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that ARCH Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly (iminoimidocarbonyliminoimido-carbonyliminohexamethylene) hydrochloride (CAS Reg. No. 32289–58–0) as an antimicrobial agent in the manufacture of food-contact paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Elizabeth R. Sanchez, Center for Food Safety and Applied Nutrition (HFS 275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1239.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4764) has been filed by ARCH Chemicals, Inc., 1955 Lake Park Dr., suite 100, Smyrna, GA 30080. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* and § 176.180 *Components of paper and paperboard in contact with dry food* to provide for the safe use of poly (iminoimidocarbonyliminoimido-carbonyliminohexamethylene) hydrochloride (CAS Reg. No. 32289–58–0) as an antimicrobial agent in the manufacture of food-contact paper and paperboard.

The agency has determined under 21 CFR 25.32(q) 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.

Dated: January 25, 2006.

Laura M. Tarantino,

Director, Office of Food Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E6–2137 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006F–0059]

Danisco USA, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Danisco USA, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant and texturizer in all foods, except meat and poultry.

DATES: Submit written or electronic comments on the petitioner's environmental assessment by March 17, 2006.

ADDRESSES: Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1302.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6A4763) has been filed by Danisco USA, Inc., 440 Saw Mill River Rd., Ardsley, NY 10502–2605. The petition proposes to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry. The proposed amendment would consolidate all existing food use categories and permit additional uses not allowed by the existing regulation.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment. Interested persons may submit to the Division of Dockets Management written or electronic comments by March 17, 2006. Two copies of any written 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: January 25, 2006.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E6–2130 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0505]

Guidance for Industry and Food and Drug Administration; Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System; 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: Implantable Intra-Aneurysm Pressure Measurement System.'' This guidance document describes a means by which the implantable intra-aneurysm pressure measurement system 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 these device types into class II (special controls). This guidance document is immediately in effect as the special control for implantable intra-aneurysm pressure measurement

systems, 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: Implantable Intra-Aneurysm Pressure Measurement System'' 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: Nelson Anderson, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8282, ext. 171.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying an implantable intra-aneurysm pressure measurement system into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for implantable intra-aneurysm pressure measurement systems.

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 into class III under section 513(f)(1) of the act, request FDA to classify the device under the 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 issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. On August 4, 2005, FDA classified the implantable intra-aneurysm measurement system into class III, because it was not substantially equivalent to a device that was introduced into interstate commerce for commercial distribution before May 28, 1976. On August 9, 2005, CardioMEMS, Inc., submitted a petition requesting classification of the CardioMEMS EndoSensor System under section 513(f)(2) of the act to be classified into class II. After review of the information submitted in the petition, FDA determined that the CardioMEMS EndoSensor System can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device. 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 (21 CFR 10.115). The guidance represents the agency's current thinking on implantable intra-aneurysm pressure measurement systems. 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: Implantable Intra-Aneurysm Pressure Measurement System'' by fax machine, call the Center for Devices and Radiological Health (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 (1589) 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 U.S.C. 3501–3520). The collections of information in this guidance document have been approved under OMB Control. No. 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: February 6, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–2142 Filed 2–15–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0420]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices: Radiology Devices; Class II Special Controls Guidance Document: Bone Sonometers; Availability

AGENCY: Food and Drug Administration, HHS.