DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95G–0009]

The American Dairy Products Institute; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 1G0371) proposing to affirm that the use of whey protein isolate and dairy product solids is generally recognized as safe (GRAS) as direct human food ingredients. Those food ingredients were redefined from the original submission containing specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

FOR FURTHER INFORMATION CONTACT: Arletta M. Beloian, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3082.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 3, 1995 (60 FR 6713), FDA announced that a petition (GRASP IG0371) had been filed by The American Dairy Products Institute, 130 North Franklin St., Chicago, IL (c/o Keller and Heckman), Washington, DC. This petition proposed that the use of whey protein isolate and dairy product solids as direct ingredients in food be affirmed as GRAS.

The American Dairy Products Institute has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 21, 2000.

Alan M. Rulis,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1165]

Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This guidance describes the types of information that should be submitted in a premarket notification to support a decision of substantial equivalence for an extracorporeal shock wave lithotripter indicated for the fragmentation of kidney and ureteral calculi. Elsewhere in this issue of the **Federal Register**, FDA is reclassifying renal and ureteral extracorporeal shock wave lithotripters from class III (premarket approval) to class II (special controls).

DATES: Submit written comments at anytime.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (CDRH) (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

In 1998, FDA initiated proceedings to reclassify the extracorporeal shock wave lithotripter for fragmentation of kidney and ureteral calculi from class III (premarket approval) to class II (special controls). To facilitate this reclassification, FDA prepared the document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This document is the special control that has been established to support reclassification to class II, and also provides general guidance to industry on the content of premarket notifications for these devices.

On July 30, 1998, a meeting of the Gastroenterology and Urology Devices Advisory Panel (the Panel) was held to seek its recommendations on this proposed reclassification, including advice on special controls and the content of premarket notifications. The Panel unanimously voted to reclassify the extracorporeal shock wave lithotripter for the fragmentation of kidney and ureteral stones into class II. Comments from the Panel have been incorporated into this guidance document.

In the **Federal Register** of February 8, 1999 (64 FR 5987 to 5996), FDA published its proposal to reclassify the extracorporeal shock wave lithotripter for fragmentation of kidney and ureteral calculi to class II, as well as its announcement of the availability of the draft document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' (64 FR 6100 to 6101). Both the proposed reclassification and the notice of availability provided an opportunity for public comment, which closed May 10, 1999.

Based on the comments received on the draft guidance document, the following substantive changes have been incorporated into the revised version being made available at this time:

1. Section 8.D (Clinical Performance Testing) was revised to more clearly state the recommended sample size. The guidance document now states that the study should enroll a total of 20 patients

with urinary stone disease at 2 investigational sites.

2. Section 8.D (Clinical Performance Testing) was revised to state a post-procedure followup time range of 48 hours to 2 weeks (previously recommended as 1 week).

3. Section 9 (Labeling) was revised to: (1) Correctly cite the agency's authority under the Federal Food, Drug, and Cosmetic Act, and (2) reword the precaution statement.

Elsewhere in this issue of the **Federal Register**, FDA is publishing the final regulation reclassifying the extracorporeal shock wave lithotripter for fragmentation of kidney and ureteral calculi to class II (special controls).

II. Significance of Guidance

This guidance document represents the agency's current thinking on extracorporeal shock wave lithotripters indicated for the fragmentation of kidney and ureteral calculi. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' via your fax machine, 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 and enter the document number 1226 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 access to the Internet. Updated on a regular basis, the CDRH home page includes the document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance. 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 12, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1274]

Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997.'' This document provides guidance for industry on FDA's interpretation of the FDA Modernization Act of 1997 (FDAMA). The document describes how the Center for Devices and Radiological Health (CDRH) will apply the new provision and explains why FDA, through CDRH, has adopted this approach.

DATES: Submit written comments by November 7, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by November 7, 2000. Submit written comments to the contact person listed below after November 7, 2000. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Robert R. Gatling, Jr., Center for Devices and Radiological Health (HFZ–401), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

Section 216 of FDAMA amended section 520(h)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(h)(4)). Under the new provision, FDA can use certain information, contained in approved premarket approval applications (PMA's), 6 years after the application has been approved to:

1. Approve another PMA;

2. Determine whether a Product Development Protocol (PDP) has been completed;

3. Establish a performance standard or a special control; or

4. Classify or reclassify another device.

Information available for the agency to use would include clinical and nonclinical tests or studies in the application that were used to demonstrate safety and effectiveness. However, it would exclude trade secret information such as manufacturing methods or device composition.

This provision replaced the previous section 520(h)(4) of the act, which was added by the Safe Medical Devices Act of 1990 (SMDA) and established the