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: This notice concerns 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.


SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of February 8, 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The American Dairy Products Institute has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).


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

[FR Doc. 00–20086 Filed 8–8–00; 8:45 am]

BILLING CODE 4160–01–F

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: This notice concerns a petition 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.

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.

I. Background

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 expected 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
titled “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

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.
[FR Doc. 00–20087 Filed 8–8–00; 8:45 am]
BILLING CODE 4160–01–F

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
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. 360(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