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.

[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 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

four-of-a-kind rule for use of data in PMA's. Under the four-of-a-kind rule, the agency could use data contained in any filed PMA 1 year after FDA had approved the fourth device of a kind. The four-of-a-kind provision also contained detailed rules for its application to data in applications approved before the SMDA's effective date. The SMDA provision replaced section 520(h)(3) of the act, which was enacted with the Medical Device Amendments of 1976 (MDA). Under the MDA, the agency could not use data in one PMA to establish the safety or effectiveness of any device other than the one for which the data was submitted.

FDA is issuing this guidance in response to conflicting interpretations of section 216 of FDAMA advanced by regulated industry. FDA has concluded that it will apply section 216 to free data only in PMA's approved after November 28, 1990, the date of enactment of the SMDA. The agency does not intend to use data in PMA's approved before that date other than data that would be available to FDA without the authority granted by section 216 of FDAMA, such as published studies. The guidance also sets forth procedures for identifying and using data available under section 216 of FDAMA.

II. Significance of Guidance

This guidance document represents the agency's current thinking on section 216 of FDAMA. 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 being issued as a Level 1 guidance consistent with GGP's. This guidance document is effective immediately because it interprets a new statutory requirement that has been in effect since February 19, 1998.

III. Electronic Access

In order to receive ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,'' 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 (1135) 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 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, ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,'' 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 submit to the Dockets Management Branch (address above) written comments regarding this immediately-in-effect guidance by November 7, 2000. Submit to the contact person (address above) written comments regarding this guidance after November 7, 2000. 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 27, 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–1408]

International Conference on Harmonisation; Draft Guidance on Principles for Clinical Evaluation of New Antihypertensive Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E12A Principles for Clinical Evaluation of New Antihypertensive Drugs.'' The draft guidance, prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), was designated an ICH principle document. The draft guidance is intended to provide general principles for the clinical evaluation of new antihypertensive drugs. It describes the core principles accepted in the three ICH regions for the evaluation of new antihypertensive drugs, including assessments of efficacy and safety and choice of study population.

DATES: Submit written comments on the draft guidance by November 7, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Robert Temple, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of