Dated: October 28, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29750 Filed 11–5–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0896]

Guidances for the Medical Device Industry on PMA Shell Development and Modular Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review.'' This guidance describes a new program for the submission and review of premarket approval applications (PMA's) in a modular format, termed the ''PMA Shell.'' FDA is issuing this document as part of its commitment to improve the PMA development and review processes.

DATES: Written comments concerning this guidance must be received by February 4, 1999.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review'' (on a 3.5'' diskette) 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 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 on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ashley A. Boulware or Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–460 or HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053 or 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Despite a marked improvement in device approval times, FDA's Center for Devices and Radiological health (CDRH) is committed to substantial improvement of the PMA development and review processes. Often FDA's involvement with the product has been greatest during review of the PMA, which is at the end of the process. This new program involves the development of a plan for modular submission, termed the ''PMA Shell,'' and the submission of sections of the PMA, termed modules, to increase early and effective interactions with applicants.

The essence of the modular concept for data development, submission, review, and closure is to break the contents of a PMA into well delineated components (modules) that can be submitted over time; this is expected to be particularly applicable to the preclinical information as the clinical data are being developed. The PMA Shell is a document that is proposed by the potential PMA applicant and agreed to by CDRH. The PMA Shell is used to identify the proposed modules and the proposed contents for each module. The PMA Shell allows CDRH to prospectively determine whether each proposed module will be appropriate as a document that can be reviewed separately from other information needed to evaluate the PMA. For example, the toxicology data may be appropriate as a module, whereas labeling may not be appropriate as a module independent of the clinical study data. Modules will be submitted to CDRH for review. Once they are complete and acceptable to FDA, modules will not generally be reevaluated unless a significant safety and effectiveness issue later develops that bears on the previously reviewed module.

Through increased interaction with applicants and earlier review of data and analyses, CDRH expects this program to increase the efficiency of PMA review by reviewing and bringing to closure modules nearer to when the data are developed and when the corporate staff who developed the data should most easily be able to respond to any need for clarification of the reports.

II. Significance of Guidance

This guidance document represents the agency's current thinking on improving the PMA process. 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 satisfied 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 a Level 1 guidance consistent with GGP's.

III. Comments

Interested persons may, on or before February 4, 1999, submit to the Dockets Management Branch (address above) written comments regarding this guidance. After February 4, 1999, submit written comments regarding this guidance to the contact persons (address above). 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.

IV. Electronic Access

In order to receive ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (835) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review,'' 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.fed.gov/cdrh''. ''Guidances for the Medical Device Industry on PMA Shell Development and Modular Review'' will be available at ''http://www.fda.gov/cdrh/ode''.

Dated: October 28, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4341–N–34]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Mr. Jeff Holste, U.S. Army Corps of Engineers, Installation Support Center, 7701 Telegraph Road, Alexandria, VA 22315; (703) 428–6318; (these are not toll-free numbers).

Dated: October 29, 1998.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program Federal Register Report for 11/06/98

Unsuitable Properties

Building (by State)

Alabama

Bldg. S162
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 21984001
Status: Unutilized
Reason: Extensive deterioration

Bldg. S179
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 219840002
Status: Unutilized
Reason: Extensive deterioration

Bldg. 217
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 21984003
Status: Unutilized
Reason: Extensive deterioration

Bldg. 609
Anniston Army Depot
Anniston AL 362091–
Landholding Agency: Army
Property Number: 21984004
Status: Unutilized
Reason: Extensive deterioration

Bldg. 610
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 219840005
Status: Unutilized
Reason: Extensive deterioration

7 Bldgs.
Fort Rucker
#6007–6011, 6013–6014
Ft. Rucker Co: Dale Al 36362–
Landholding Agency: Army
Property Number: 219840006
Status: Unutilized
Reason: Extensive deterioration

4 Bldgs.
Fort Rucker
#24501, 30306, 30309, 30310
Ft. Rucker Co: Dale AL 36362–
Landholding Agency: Army
Property Number: 219840007
Status: Unutilized
Reason: Extensive deterioration