

revised our recommendations in the final guidance. All submissions for the initial licensure of a pandemic influenza vaccine should be submitted as BLAs, which will provide for a trade name and labeling specific to the pandemic vaccine. For sponsors with existing licensed seasonal inactivated or live attenuated influenza vaccines who intend to file a BLA for a pandemic influenza vaccine that utilizes the same manufacturing process, we would expect that the BLA would reference the original BLA, including the nonclinical and chemistry, manufacturing, and controls data in their original BLA. Manufacturers that do not have existing licensed influenza vaccines, or that do, but are seeking to license a pandemic influenza vaccine utilizing a different manufacturing process, may seek accelerated approval according to the provisions of 21 CFR 601.41.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338 and in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10499 Filed 5–31–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0083]

Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines,” dated May 2007. The guidance document is intended to provide to sponsors of seasonal inactivated influenza vaccines guidance on clinical development approaches to support a biologics license application (BLA). The guidance provides recommendations concerning clinical data to support traditional and accelerated license approvals for new seasonal inactivated influenza vaccines. The guidance announced in this notice finalizes the draft “Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccine” dated March 2006.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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>.

FOR FURTHER INFORMATION CONTACT:

Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines,” dated May 2007. The guidance is intended to provide to sponsors of seasonal inactivated influenza vaccines guidance on the clinical data needed to support a BLA. The approaches in the guidance apply to both nonadjuvanted and adjuvanted hemagglutinin-based seasonal vaccines, including “split virus,” subunit, and whole virus inactivated vaccines propagated in embryonated chicken eggs or cell-culture, and to recombinant hemagglutinin-based protein vaccines, and DNA vaccines that express hemagglutinin.

Licensure of seasonal inactivated influenza vaccines may be sought through either traditional or accelerated pathways. The guidance provides recommendations for clinical data to support traditional and accelerated license approvals for new seasonal inactivated influenza vaccines.

In the **Federal Register** of March 10, 2006 (71 FR 12367), FDA announced the availability of the draft guidance entitled “Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines” dated March 2006. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The changes in the final guidance include a change from the term “trivalent” inactivated influenza vaccines to “seasonal” inactivated influenza vaccines. This change was made to provide flexibility for evolving public health needs, including the development of vaccines with either more than three or less than three antigens. In addition, editorial changes were made to improve clarity.

The guidance announced in this notice finalizes the draft guidance dated March 2006.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; those in 21 CFR part 600 have been approved under OMB control number 0910–0308; and those in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (See **ADDRESSES**) written or electronic comments regarding the guidance. 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5125–N–22]

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: Kathy Ezzell, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; 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. Where

property is described as for “off-site use only” recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to John Hicks, Division of Property Management, Program Support Center, HHS, room 5B–17, 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:** Ms. Veronica Rines, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, Attn: DAIM–ZS, Rm 8536, 2511 Jefferson Davis Hwy., Arlington, VA 22202; (703)