800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Valerie A. Butler, 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 draft document entitled ''Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)'' dated July 2007. The draft guidance document discusses certain cell selection devices that minimally manipulate autologous PBSCs at the point of care for specific clinical indications, and the applicability of the requirements of 21 CFR part 1271 to such PBSCs. The guidance also discusses the submission of data intended to support approval of cell selection devices.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 812 have been approved under 0910–0078; the collections of information in 21 CFR part 814 have been approved under 0910–0231; the collections of information in 21 CFR part 820 have been approved under 0910–0073; and the collections of information in 21 CFR part 822 have been approved under 0910–0449.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft 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 draft 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 draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3659 Filed 7–23–07; 12:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Multivariate Index Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance entitled ''In Vitro Diagnostic Multivariate Index Assays.'' FDA is issuing this revised draft guidance to address the definition and regulatory status of a class of In Vitro Diagnostic Devices referred to as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). The revised draft guidance also addresses premarket and postmarket requirements with respect to IVDMIAs. The initial draft of this guidance was issued September 7, 2006.

DATES: Submit written or electronic comments on this draft guidance by August 27, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''In Vitro Diagnostic Multivariate Index Assays'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or 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 that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0694.

For further information concerning the guidance as it related to devices regulated by CBER: Martin Ruta, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 7, 2006 (71 FR 52800). FDA published a notice of availability of the initial draft guidance to address the definition and regulatory status of a class of in vitro diagnostic devices referred to as ''In Vitro Diagnostic Multivariate Index Assays (IVDMIAs).'' The initial draft guidance also addressed premarket and postmarket requirements with respect to IVDMIAs.

An IVDMIA, as defined in the draft guidance document, is a device within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). Some IVDMIAs are laboratory-developed tests (LDTs); laboratory-developed IVDMIAs are a specific subset of LDTs. While FDA has stated that ''clinical laboratories that develop (in-house) tests

are acting as manufacturers of medical devices and are subject to FDA jurisdiction under the Act,'' 62 FR 62243 to 62249 (November 21, 1997), the agency has generally exercised enforcement discretion over most standard LDTs. However, in the draft guidance, FDA recognizes that IVDMIAs include elements that are not among the primary ingredients of standard LDTs (e.g., complex, unique, interpretation functions). IVDMIAs thus do not fall within the scope of LDTs over which FDA has generally exercised enforcement discretion.

IVDMIAs raise significant issues of safety and effectiveness. These types of tests are developed based on observed correlations between multivariate data and clinical outcome, such that the clinical validity of the claims is not transparent to patients, laboratorians, and clinicians who order these tests. Additionally, IVDMIAs frequently have a high risk intended use. FDA is concerned that patients and healthcare practitioners are relying upon IVDMIAs with high risk intended uses to make critical healthcare decisions without any independent assurance that the IVDMIA has been properly clinically validated, and without any ability to assess whether the test yields clinically valid results.

With this revised draft guidance document, FDA seeks to identify IVDMIAs as a discrete category of device, and to clarify that, even when offered as LDTs, IVDMIAs must meet pre- and post-market device requirements under the act and FDA regulations, including premarket review requirements in the case of most class II and III devices.

FDA received and considered approximately 60 sets of comments on the initial draft guidance document, including comments provided at a public meeting that was held on February 8, 2007. After taking the comments into consideration, the FDA has updated the draft guidance document to provide clarifications as needed.

Certain comments on the initial draft guidance document requested that FDA undertake notice and comment rulemaking rather than issue a guidance document in order to allow sufficient opportunity for public input. In response to this concern, FDA extended the comment period on the draft guidance document from 90 days to 180 days, March 5, 2007 (71 FR 68822), and held a public meeting to provide a forum for presentations and comments on the draft guidance document. The meeting was attended by 266 people representing a cross-section of interested stakeholders including industry, consumer groups, and the medical community. FDA has carefully considered the comments it has received. Many comments reflect that stakeholders construed the definition of IVDMIAs in the initial draft guidance document to encompass a wider range of tests than FDA had intended. The initial draft guidance document has been revised to clarify the definition of an IVDMIA and to provide examples of tests that the agency does and does not consider to be IVDMIAs. This section of the draft guidance was modified so that stakeholders can more easily understand the nature of tests designated as IVDMIAs, and manufacturers can more easily determine whether their tests are IVDMIAs. However, the clarifications do not alter the scope or intent of the definition of an IVDMIA found in the initial draft guidance document.

In response to additional comments received, the revised draft guidance document now clarifies FDA regulatory mechanisms in general, such as how devices are classified and reviewed based on the risk of the intended use, how laboratory-developed IVDMIAs should be labeled, and how manufacturers can update and improve cleared or approved devices using existing mechanisms within the regulatory framework. These existing mechanisms enable manufacturers to bring innovative new tests to the market and ensure that they can be updated and improved as new scientific information becomes available. While this information is generally available in existing regulations, guidance documents, and on the FDA Web site, the revised draft guidance provides a summary of this information with a focus on IVDMIAs in order to assist those stakeholders who are not familiar with existing FDA requirements.

In other comments, some stakeholders expressed concern that requiring FDA regulatory compliance for IVDMIAs has the potential to discourage the development of new tests for rare diseases. A manufacturer of an IVDMIA for a disease or condition that affects small patient populations may find that research and development costs exceed market returns. The draft guidance has been revised to indicate FDA's intent to exercise enforcement discretion for laboratory-developed IVDMIAs that are intended to diagnose rare diseases (i.e., IVDMIAs that meet the definition of Humanitarian Use Devices under 21 CFR part 814 Subpart H).

Finally, the draft guidance document clarifies that laboratories that manufacture IVDMIAs should follow the Medical Device Reporting requirements for manufacturers, 21 CFR part 803 for their IVDMIA device(s). As in the initial draft guidance, the revised draft guidance indicates that FDA intends to issue guidance to assist laboratories that manufacture IVDMIAs in complying with the Quality System regulation (QS), 21 CFR part 820. In response to comments that expressed concern about coming into compliance with the QS regulation, the revised draft guidance indicates that until such a final guidance is published, FDA intends to exercise enforcement discretion with regard to post-market QS requirement enforcement for laboratories that manufacture IVDMIAs, recognizing that some Clinical Laboratory Improvement Amendments of 1988 (CLIA' 88) requirements may partially fulfill corresponding QS regulation requirements.

FDA is issuing this revised draft in order to gather significant new comments before issuing a final version of the guidance. Because the agency believes it has addressed the most important concerns raised by the comments it received on the initial draft, and because it is important to issue a final guidance to provide clarity for stakeholders, FDA is providing a comment period of 30 days following publication of this document.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on IVDMIAs. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''In Vitro Diagnostic Multivariate Index Assays,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1610 to identify the guidance you are requesting.

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 Internet access. Updated on a regular basis, the CDRH home page includes 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 Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that 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 the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notifications (21 CFR part 807, subpart E, OMB control number 0910–0120) premarket approval applications (21 CFR part 814, OMB control number 0910–0231), investigational device exemptions (21 CFR part 812, OMB control number 0910–0078), quality system regulation (21 CFR part 820, OMB control number 0910–0073), and medical device reporting (21 CFR part 803, OMB control number 0910–0437). The labeling provisions addressed in this guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before August 27, 2007. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3660 Filed 7–23–07; 12:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0333]

Guidance; Emergency Use Authorization of Medical Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Emergency Use Authorization of Medical Products.'' The guidance explains FDA's policies for authorizing the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency. This guidance finalizes the draft guidance published in the **Federal Register** of July 5, 2005 (70 FR 38689).

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

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–827–5671. 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*. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charlotte Christin, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, government agencies, and FDA staff entitled ''Emergency Use Authorization of Medical Products.'' This guidance describes the agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Public Law 108–276).

Section 564 of the act provides for authorization of ''emergency use'' of a medical product, after a declaration of emergency justifying an authorization is issued by the Secretary of Health and Human Services (the Secretary) based on one of the following grounds: A determination by the Secretary of Homeland Security that there is an actual or potential ''domestic emergency;'' a determination by the Secretary of Defense that there is an actual or potential ''military emergency;'' or a determination by the Secretary that there is a public health emergency under section 319 of the Public Health Service Act that affects or has the significant potential to affect national security. The Commissioner of Food and Drugs may issue an EUA for an unapproved drug, device, or biologic, or an unapproved use of an approved drug, device, or biologic, during a declared emergency if the statutory criteria set forth in section 564 of the act are met.

On July 5, 2005, FDA published for comment in the **Federal Register** a draft of this guidance. Comments received from industry, associations, health care professionals, consumers, and staff of other Federal agencies have been taken into consideration in finalizing this guidance. Changes are based on a thorough review of all comments received. As revised, the guidance includes a more detailed discussion of the scope of preemption (where applicable) and also provides points of contact for further information on several Federal liability protection and compensation programs.

This guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It represents the agency's current thinking on emergency use authorizations of medical products. 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.