manufacturers that it views certain practices as being inconsistent with the marketing of an ASR, as defined in Sec. 864.4020. As the draft guidance document explains, when an ASR is marketed in certain ways, FDA views the product as no longer being an ASR within the meaning of Sec. 860.4020.

FDA issued this draft guidance on September 7, 2006. The initial comment period on the draft guidance closes on December 6, 2006, but at the request of in vitro diagnostic device stakeholders, FDA has decided to extend the comment period for an additional 90 days, until March 5, 2007.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions,'' you may either send an email 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 1590 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 manufacturer's 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 Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20030 Filed 11–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0310]

Guidance for Industry: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events; 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: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events,'' dated November 2006. The guidance document provides sponsors of gene therapy studies with recommendations regarding collection of data on delayed adverse events in subjects who have been exposed to investigational gene therapy products. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events,'' dated August 2005, and supplements the recommendations for study subject long-term follow-up in the ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' (Retroviral Vector guidance), dated November 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: Brenda R. Friend, 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: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events,'' dated November 2006. This guidance provides to sponsors of gene therapy studies recommendations on the following: (1) Methods to assess the risk of gene-therapy-related delayed adverse events following exposure to investigational gene therapy products, (2) guidance for determining the likelihood that long-term follow-up observations on study subjects will provide scientifically meaningful information, and (3) specific advice regarding the duration and design of long-term follow-up observations.

In the **Federal Register** of August 23, 2005 (70 FR 49296), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events,'' dated August 2005. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes the following: (1) Clarification on topics not included in the guidance; (2) revised recommendations for preclinical study design to assess vector biodistribution and persistence; and (3) revised recommendations for data collection and data reporting in trials involving integrated vectors (e.g., retroviral vectors). The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events,'' dated August 2005. This guidance also supplements the recommendations in the Retroviral Vector guidance, dated November 2006, for study subject long-term follow-up.

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 the Investigational New Drug Application (IND) regulations (21 CFR part 312) have been approved under OMB control number 0910–0014; the Good Laboratory Practice regulations (21 CFR part 58) have been approved under OMB control number 0910–0119.

III. Comments

Interested persons maysubmit 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 may be seen 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: November 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20129 Filed 11–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff on In Vitro Diagnostic Multivariate Index Assays; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.'' The agency announced the availability of this draft guidance in the **Federal Register** of September 7, 2006 (71 FR 52800). The initial comment period closes on December 6, 2006. To provide interested persons additional time to review and submit comments on the draft guidance, the agency has decided to extend the comment period.

DATES: Submit written or electronic comments on this draft guidance by March 5, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on 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. 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 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, 240–276–0490, ext. 162.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on the ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.'' This draft guidance is intended to provide clarification on FDA's approach to regulation of in vitro diagnostic multivariate index assays.

The agency issued this draft guidance on September 7, 2006. The initial comment period on the draft guidance closes on December 6, 2006, but at the request of in vitro diagnostic device stakeholders, the agency has decided to extend the comment period for an additional 90 days, until March 5, 2007.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on 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 manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information.