on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Paul E. Levine, Jr., 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: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases,'' dated September 2006. This draft guidance provides manufacturers of viral vaccines with recommendations for the characterization and qualification of cell substrates and viral seeds used for the production of viral vaccines for human use. These recommendations may be used to support a Biologics License Application or an application for an Investigational New Drug.

This draft guidance, when finalized, is intended to replace the information specific to viral vaccines, but does not replace information on other biological products, contained in the 1993 document entitled, ''Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals.'' This draft guidance, when finalized, is also intended to supplement recommendations on the production of viral vaccines for the prevention and treatment of infectious diseases, provided in the International Conference on Harmonisation (ICH) documents entitled ''Guidance for Industry: Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin'' dated September 1998 (63 FR 51074; September 24, 1998) and ''Q5D Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products'' (63 FR 50244; September 21, 1998).

The scope of this draft guidance document is limited to cell substrates of human and animal origins and does not cover characterization of unicellular organisms, such as bacteria or yeast. This draft guidance also applies to the characterization and qualification of viral seeds. This draft guidance does not supersede the general requirements for biologicals described in Title 21 Code of Federal Regulations (CFR), part 210, part 211, part 601, nor part 610.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent FDA's current thinking on the identified topic. It does not create nor 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

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). Most of the collections of information to which this draft guidance refers are covered by parts 601 (on BLAs) and 21 CFR part 312 (on INDs), and were approved under OMB Control No. 0910–0338 and 0910–0014, respectively. For the remaining referenced collections of information, those in 21 CFR 640.3 and 640.63 have been approved under OMB control numbers 0910–0116; those in part 211, including § 211.160(b), have been approved under OMB control number 0910–0139; and those in 21 CFR part 58 have been approved under OMB Control No. 0910–0119.

III. Comments

This 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: September 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1999D–0054, 2001D–0475, and 2003D–0364] (formerly Docket Nos. 99D–0054, 01D–0475, and 03D–0364, respectively)

Guidances on Providing Regulatory Submissions in Electronic Format; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research is announcing the withdrawal of three guidances for industry: ''Providing Submissions in Electronic Format—NDAs,'' ''Providing Regulatory Submissions in Electronic Format—ANDAs,'' and ''Providing Regulatory Submissions in Electronic Format: Annual Reports for NDAs and ANDAs.'' These guidances are being withdrawn because they are no longer consistent with more recent guidance and no longer reflect the agency's preferred format for receiving electronic submissions.

DATES: September 29, 2006.

FOR FURTHER INFORMATION CONTACT: Armando Oliva, Center for Drug Evaluation and Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1512, e-mail: *armando.oliva@fda.hhs.gov*, or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401

Rockville Pike, Rockville, MD 20852, 301–827–0373, e-mail: *robert.yetter@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

During the past decade, FDA has been working to expand its ability to receive and review marketing applications electronically. In addition, the agency has been working through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to harmonize the formats being used for marketing applications.

Beginning in 1999, FDA issued two guidances and one draft guidance for industry that made recommendations to applicants wishing to submit applications to FDA in electronic format: (1) ''Providing Regulatory Submissions in Electronic Format—NDAs'' (e-NDA guidance) (64 FR 4432, January 28, 1999), (2) ''Providing Regulatory Submissions in Electronic Format—ANDAs'' (e-ANDA guidance) (67 FR 43331, June 27, 2002), and (3) ''Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications'' (draft) (68 FR 51788, August 28, 2003). In general, these guidances recommended submitting documents as portable document files (PDF), electronic data/case report tabulations as SAS transport files, and the NDA table of contents in PDF format. In the meantime, however, the FDA adopted the ICH Common Technical Document (CTD) headings and subheadings for marketing applications. ICH then issued specifications for the electronic version of the CTD (e-CTD).

In October 2005, FDA issued the guidance ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the e-CTD Specifications'' (the e-CTD guidance) (70 FR 60842; October 19, 2005). This guidance differs from the e-NDA and e-ANDA guidances in one significant aspect: The application table of contents is no longer submitted as a PDF file, but is submitted as an XML (extensible markup language) file. This XML file has numerous advantages over the older PDF format, most significant of which is the ability to update the application table of contents automatically as new amendments are received. With the e-CTD format, sponsors and reviewers now have access to a real-time, up-to-date, cumulative table of contents that provides easy and immediate access to all files included in an application, regardless of when they were included, or in what submission they are located. This has never previously been possible. Another advantage is that the table of contents can be displayed in various ways, allowing discipline-specific views of an application, further promoting review efficiency. This is especially important for agency review staff. For example, although all portions of an application are always available to all reviewers, a chemist would be interested in different portions of the application than a clinical reviewer. The XML table of contents permits reviewers to view the application in a manner that makes the most sense to support their particular review activity.

Despite the release of the e-CTD guidance describing the use of the XML format, FDA has continued to make all three guidances available with their differing recommendations. As a result, applicants have had three choices when submitting a marketing application electronically: (1) Use the e-NDA/e-ANDA format, (2) use the e-CTD format, or (3) use what we call a ''hybrid'' submission (the older e-NDA format with the table of contents organized using the newer CTD headings). In addition, FDA still receives submissions that are a combination of paper and electronic formats. Of course, this would not be appropriate for sponsors who are using the e-CTD format, as doing this would negate the intent of having all portions of the application readily available for review via the XML table of contents. A result of having this variety of choices is confusion and frustration for industry, who are not receiving consistent recommendations about how to submit marketing applications. It is also confusing and frustrating for our review staff. In addition, our willingness to receive applications in a variety of different forms has forced the agency to maintain expensive and duplicative processes and systems for receiving and archiving these various application types.

II. Withdrawal of Guidances

The e-CTD format is preferred by FDA because it is more efficient than the other choices and consistent with FDA's technical capabilities. The e-CTD format is also the preferred ICH format. As a result, the agency is withdrawing the earlier guidances. In addition, we will remove references to these guidances from the electronic submissions docket on December 31, 2007. Further information on providing regulatory submissions in electronic format can be found on Docket No. 1992S–0251 (formerly Docket No. 92S–0251) (*http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm*). We are recommending that sponsors wishing to submit applications electronically use the most efficient and internationally agreed to formats recommended in our most recent guidance.

Although the Center for Biologics Evaluation and Research (CBER) supports the use of the e-CTD format and encourages its sponsors to use this format when creating its submissions, CBER also recognizes that in certain situations a sponsor may not be capable of providing submissions in that format at this time. Therefore, CBER recommends that sponsors who cannot use the e-CTD format consult guidance for industry ''Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA) / Establishment License Application (ELA) and New Drug Application (NDA)] (11/12/1999) (available online at *http://www.fda.gov/cber/esub/esubguid.htm*).

Dated: September 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms (OMB No. 0915–0043 Extension)

The Health Education Assistance Loan (HEAL) program continues to administer and monitor outstanding