

(the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 16-640, held by Bristol-Myers Squibb, and initially approved on August 3, 1973. QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 19-669, also held by Bristol-Myers Squibb, and initially approved on December 5, 1988. QUESTRAN and QUESTRAN LIGHT are indicated as adjunctive therapy for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoprotein cholesterol) who do not respond adequately to diet.

In a letter dated May 31, 2012, Bristol-Myers Squibb notified FDA that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were

being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated June 19, 2012 (Docket No. FDA-2012-P-0649), under 21 CFR 10.30, requesting that the Agency determine whether QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address QUESTRAN LIGHT, that version of the drug product has also been discontinued. On our own initiative, we have also determined whether QUESTRAN LIGHT was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that either product was withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to QUESTRAN or QUESTRAN LIGHT. Additional ANDAs for cholestyramine and cholestyramine light for oral suspension, USP, EQ 4 g, may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that

labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 20, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0069; (Formerly FDA-2007D-0393)]

#### Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility" dated April 2013. The guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. The guidance announced in this document finalizes the draft guidance of the same title dated October 2007.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (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 electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Melissa Reisman, 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: Blood Establishment Computer System Validation in the User's Facility" dated April 2013. The guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. The guidance document describes the requirements in Title 21 Code of Federal Regulations that apply to blood establishment validation of systems, and FDA's recommendations for the validation of systems. While the guidance may provide manufacturers of blood establishment computer software (BECS) with information about validation of computer systems in the user's facility, the guidance does not address the software manufacturer's validation responsibilities or the submission of a 510(k) premarket notification for BECS.

In the **Federal Register** of October 29, 2007 (72 FR 61171), FDA announced the availability of the draft guidance of the same title dated October 2007. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2007.

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 606.100(b) and 606.160 have been approved under OMB control number 0910-0116. The collections of information in 21 CFR 211.68 and 211.100 have been approved under OMB control number 0910-0139.

**III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent applications listed below

may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Infectious Hepatitis E Virus Genotype 3 Recombinants—Prospective Vaccine Candidates and Vector System**

*Description of Technology:* This technology is a recombinant, infectious genotype 3 Hepatitis E virus (HEV) that has been adapted to grow in cell culture and can potentially be used to develop vaccines against HEV or as a vector system to insert exogenous sequences into HEV. The virus (strain Kernow-C1, genotype 3) originated from a chronically infected human subject and was adapted to grow in human hepatoma cells. The adapted virus is unique in that it contains an insertion of a portion of a human ribosomal protein in Open Reading Frame 1 of the virus. Desired exogenous sequences can potentially be placed in lieu of the insert without inactivating the virus.

Infection by HEV is a relevant health issue in a number of developing countries and is also an emerging food-borne disease of industrialized countries. Genotype 1 and 2 infections are found exclusively in humans while genotype 3 and 4 viruses have been found not only in humans, but also swine, deer, mongoose, cattle, and rabbits. In particular, genotype 3 and 4 viruses are ubiquitously found in swine and undercooked pork is thought to be one of the sources of infection for cases of human infections in industrialized countries.

*Potential Commercial Applications:*

- An infectious, recombinant HEV genotype 3 cDNA clone that could potentially be developed into a vaccine candidate.

- HEV Vector Platform—Desired exogenous sequences can be inserted into the viral genome without inactivating the virus.

*Competitive Advantages:*

- Most of the HEV vaccines under development are subunit based while the subject technology could potentially be developed into a live, attenuated virus based vaccine.

- Ability to insert exogenous sequences into the viral genome without inactivating the virus makes this subject technology a potential HEV based vector platform.

*Development Stage:*

- Early stage.