level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice relates to documents that have been developed by two of the Study Groups (1 and 3).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidelines that could help lead to harmonization. As a result of its efforts, this group has developed final document GHTF/SG1/N011:2008. GHTF/SG1/N011:2008 ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)'' is intended to provide information on the content of the STED to be assembled and submitted to a Regulatory Authority (RA) or Conformity Assessment Body (CAB) for premarket review, and for use postmarket to assess continuing conformity to GHTF Study Group 1's document, GHTF/SG1/N41R9:2005, ''Essential Principles of Safety and Performance.''

Study Group 3 was initially tasked with the responsibility of developing documents on Quality Systems. As a result of their efforts, this group has developed proposed document SG3(PD)N17R7. The proposed document SG3(PD)N17R7 entitled, ''Quality Management System—Medical Devices—Guidance on the Control of Products and Services Obtained From Suppliers'' provides information for medical device manufacturers on control of products and services obtained from suppliers.

II. Significance of Documents

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particular where they are not consistent with current practices for the manufacturer of products distributed in the United States.

III. Electronic Access

Persons interested in obtaining a copy of these documents may do so by using the Internet. The Center for Devices and Radiological Health (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. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16000 Filed 7–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0157] (formerly Docket No. 2005D–0286)

Guidance for Industry: Current Good Manufacturing Practice for Phase 1 Investigational Drugs; 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: CGMP for Phase 1 Investigational Drugs'' dated July 2008. The guidance provides assistance in applying relevant current good manufacturing practice (CGMP) requirements of the Federal Food, Drug, and Cosmetic Act (the act) to the manufacture of most investigational new drugs, including biological drugs, used in phase 1 clinical trials. FDA is issuing this guidance concurrently with a final rule published elsewhere in this issue of the **Federal Register** specifying that compliance with FDA's CGMP regulations is not required for most investigational drugs that are manufactured for use in phase 1 clinical trials. Therefore, FDA is recommending the approaches outlined in this guidance for complying with the statutory CGMP requirements in the act. The guidance announced in this notice finalizes the draft guidance entitled ''INDs—Approaches to Complying with CGMP During Phase 1'' dated January 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 Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9047, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5000.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: CGMP for Phase 1 Investigational Drugs'' dated July 2008. This guidance provides assistance in applying CGMP required under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) in the manufacture of most investigational new drugs used in phase 1 clinical trials (phase 1 investigational drugs). The guidance is being issued concurrently with a final rule that specifies that the manufacture of most investigational new drugs manufactured for use in phase 1 clinical trials do not have to comply with the specific regulatory requirements in part 211 (21 CFR part 211).

Because a phase 1 clinical trial initially introduces an investigational new drug into human subjects, appropriate CGMP helps ensure subject safety. This guidance applies, as part of CGMP, quality control principles to the manufacture of phase 1 investigational drugs (i.e., interpreting and implementing CGMP consistent with good scientific methodology), which foster CGMP activities that are more appropriate for phase 1 clinical trials, improve the quality of phase 1 investigational drugs, and facilitate the initiation of investigational clinical trials in humans while continuing to protect trial subjects. For the manufacture of phase 1 investigational drugs described in this guidance (see section III of the guidance), this guidance will replace the guidance issued in 1991 (56 FR 7048, February 21, 1991) entitled ''Preparation of Investigational New Drug Products (Human and Animal)'' (the 1991 guidance). However, the 1991 guidance still applies to the manufacture of investigational new products (human and animal) used in phase 2 and phase 3 clinical trials.

In the **Federal Register** of January 17, 2006 (71 FR 2552), FDA announced the availability of the draft guidance entitled ''INDs—Approaches to Complying with CGMP During Phase 1'' dated January 2006. FDA received a moderate number of comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated January 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 this guidance for part 211 have been approved under OMB control number 0910–0139.

III. Comments

Interested persons may 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 9, 2008.

Jeffrey Shuren,

Associate Comissioner for Policy and Planning.

[FR Doc. E8–16002 Filed 7–14–08; 8:45 am]

BILLING CODE 4160–01–S

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.

ADDRESSES: 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.

Neutralization of Hepatitis C Virus (HCV)

Description of Technology: Available for licensing and commercial development are anti-hepatitis C virus (HCV) vaccines, therapeutics and inhibitors. The invention is based on mapping studies conducted by the inventors of two epitopes within HCV E2: epitope I and epitope II. It has been discovered that epitope I is involved in virus neutralization but that epitope II mediates antibody interference; probably an adaptation of the virus to obfuscate the immune system. The present invention provides compositions and methods for treating and or preventing HCV infection caused by HCV. The invention is directed to a HCV E2 polypeptide substitution of