regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, and the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is now being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of July 20, 2000 (65 FR 45085), FDA published a draft revised tripartite guidance entitled ''Q3A(R) Impurities in New Drug Substances.'' The notice gave interested persons an opportunity to submit comments by September 18, 2000. The draft revised guidance was a revision of ICH guidance on the same topic published in the **Federal Register** of January 4, 1996 (61 FR 372).

After consideration of the comments received and revisions to the guidance by the Quality Expert Working Group of the ICH, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 6, 2002.

ICH Q3A(R) provides guidance on the information for drug marketing registration regarding the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered within the three regions of the EC, Japan, and the United States. The guidance is not intended to apply to new drug substances used during the clinical research stage of development. The following types of drug substances are not covered in this guidance: Biological/biotechnological, peptide, oligonucleotide, radiopharmaceutical, fermentation products and semisynthetic products derived therefrom, herbal products, and crude products of animal or plant origin.

Impurities in new drug substances are addressed in the guidance from two different perspectives: (1) Chemistry aspects—classification and identification of impurities in specifications, report generation, listing of impurities in specifications, and a brief discussion of analytical procedures; and (2) safety aspects—guidance for qualifying those impurities that were not present, or were present at substantially lower levels, in batches of the new drug substance used in safety and clinical studies.

The ICH Q3A guidance was revised to add information to certain sections and to provide clarification to other sections of the previous guidance. The most important sections that have been revised are:

- The text on reporting, identification, and qualification thresholds.
- The text on listing impurities in specifications to provide a clear distinction between ICH Q3A (listing impurities) and ICH Q6A (setting specifications).
- The deletion of the exception to conventional rounding practice, i.e., the provision recommending no rounding up to 0.1 percent for values between 0.05 and 0.03 percent.
- Attachment 2—an illustration of reporting impurity results for identification and qualification in an application.
- Attachment 3—a decision tree for identification and qualification.
- Additions and revisions to the previous glossary include definitions for the terms ''unspecified impurity,'' ''identification threshold,'' and ''qualification threshold.''
- References to more recently published ICH guidances entitled ''Q3B(R) Impurities in New Drug Products,'' ''Q3C Impurities: Residual Solvents,'' and ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.''

Minor editorial changes were made to improve the clarity and consistency of the document.

This guidance represents the agency's current thinking on impurities in new drug substances. 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. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed comments are to be submitted, 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. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/publications.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: February 4, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–3352 Filed 2–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0002]

Medical Devices; Export Certificates; FDA Export Reform and Enhancement Act of 1996; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the new fees the agency will assess for issuing export certificates for devices. The FDA Export Reform and Enhancement Act of 1996 (EREA) provides that any person who exports a device may request that FDA certify in writing that the exported device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification and that FDA may charge up to $175 for each certification that is issued within

the 20 days. FDA's costs to process the device certificates have increased since the inception of the export certification program for devices. Because of the increase, FDA is raising the fees for device export certificates accordingly. This document explains the costs included in the export certification program for devices. This is the first increase of the device export certificate fee under the EREA since the initial fee was established in 1996.

DATES: The fees described in this document for export certificates for devices will be effective March 1, 2003. Submit written or electronic comments by March 13, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Leila M. Craddock, Office of Compliance, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–4555, ext. 110, FAX 301–594–4715.

SUPPLEMENTARY INFORMATION:

I. Background

The EREA became law on April 26, 1996 (Public Law 104–134, amended by Public Law 104–180, August 6, 1996). The principal purpose of this law is to expedite the export of FDA regulated products, both approved and unapproved, through amendments to sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382). Section 801(e)(4) of the act provides that any person who exports a drug, animal drug, or device may request that FDA certify in writing that the exported drug, animal drug, or device meets the requirements of section 801(e) or 802 of the act, or other applicable requirements of the act. Upon a showing that the product meets the applicable requirements, the law provides that FDA shall issue export certification within 20 days of the receipt of a request for such certification. It also allows FDA to collect fees of up to $175 for each certificate that is issued within the 20-day period. The focus of this notice is on export certificates issued by the Center for Devices and Radiological Health (CDRH).

The original notice on the EREA fees for export certificates was published in the **Federal Register** on November 6, 1996 (61 FR 57445), and became effective October 1, 1996. An updated resource review within CDRH has identified that recoverable costs of the device export certifications have increased since October 1996. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will meet the aggregate costs to issue device export certificates.

II. Agency Costs and Fees to be Assessed for Export Certificates

The costs of the export certification program for devices have grown since fiscal year 1997 (FY 97), while the export certificate fee has not changed. The increased costs in the export certification program for devices are attributable to two major areas: (1) The volume of requests for certificates and (2) the increase in payroll costs over the past 6 years. These costs account for the major differences between FY 97 and the current year.

The volume of requests for certificates has increased by 100 percent since FY 97. In order to meet this increased volume of requests, the staff size has grown accordingly. In addition, CDRH's average salary has increased by 37 percent during the same time period. Table 1 of this document shows the increase in certificates from FY 97 to FY 02 (the number of certificates for 2002 was estimated):

TABLE 1.—NUMBER OF EXPORT CERTIFICATES FROM FISCAL YEAR 1997 TO FISCAL YEAR 2002

Fiscal Year (FY)	Total Certificates
FY 97	11,140
FY 98	17,107
FY 99	18,954
FY 00	21,292
FY 01	23,737
FY 02	23,000[1]

[1] Estimated.

The estimated costs of the export certification program for devices in FY 03 are: $533,000 for payroll and $267,000 for operating expenses. There are four recoverable cost categories for preparing and issuing export certificates. They are:

1. Direct personnel for research, review, tracking, writing, and assembly;
2. Purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life;
3. Billing and collection of fees; and
4. Overhead and administrative support.

As mentioned previously in this document, the agency may charge up to $175 for each certificate. Certificates for some classes of products cost the agency more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost the agency less than $175. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced agency costs for preparing those certificates.

The following fees will be assessed starting March 1, 2003, for device export certificates:

TABLE 2.—FEES FOR FIRST AND SUBSEQUENT EXPORT CERTIFICATES

Type of Certificate	Fee (dollars)
First certificate	175
All subsequent certificates issued for the same product(s) in response to the same request.	15

The fee for issuing the first export certificate for a device product is now at the maximum allowable amount. This fee is now consistent with the export certification fees assessed since FY 97 by all other FDA centers who provide export certification. The fees for issuing subsequent certificates continue to differ among the centers, based on varying costs. The agency expects this new fee schedule for device export certificates to remain constant for at least several years. However, if there is an increased cost to the agency in issuing device export certificates, the fee for subsequent certificates for device products may be increased in the future.

III. Request for Comments

Although the EREA does not require that FDA solicit comments on the assessment and collection of fees for export certificates, FDA is inviting comments from interested persons in order to have the benefit of additional views.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two hard copies of any written comments, except that individuals may submit one hard 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 30, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–3350 Filed 2–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: HRSA Competing Training Grant Application, Instructions and Relating Regulations (OMB No. 0915–0060)—Revision

The Health Resources Services Administration uses the information in the application to determine the eligibility of applicants for awards, to calculate the amount of each award and to judge the relative merit of applications. The application contains a basic set of general instructions as well as program-specific instructions which includes the detailed description of the project. The budget is negotiated for all years of the project period based on this application.

The burden estimate is as follows:

Form	Number of respondents	Response per respondent	Total responses	Hours per response	Total burden hours
Progress Report	1,250	1	1,250	56.25	70,313

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 4, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–3298 Filed 2–10–03; 8:45 am]

BILLING CODE 4165–15–P

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 agencies 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.

Scavenger Receptor BI Targeting for the Treatment of Infection, Sepsis and Inflammation

Alexander Bocharov *et al.* (CC)

DHHS Reference No. E–008–03/0 filed 05 Nov 2002

Licensing Contact: Uri Reichman; 301/435–4616; *reichmau@od.nih.gov*

Proinflammatory bacterial cell wall components including lipopolysaccharide (LPS), lipoteichoic acid (LTA) and peptidoglycan (PGN) are major factors determining the development, progression and outcome for a number of infectious diseases. Chaperonin 60 (spn60), another bacterial component, and its human ortholog heat shock protein 60 (hsp60), also play an important role in inflammatory diseases such as arthritis and lupus erythematosus. This invention relates to the discovery that peptides with an amphipathic helical motif block cellular uptake of LPS (lipopolysaccharide) and proinflammatory responses induced by LPS, LTA (lipoteichoic acid), bacterial cpn60 (Chaperonin 60) and human hsp60 (heat shock protein 60) in vitro. These observations suggest that agents with an amphipathic motif targeting SR–BI (scavenger receptor class B type I) could potentially be used to treat sepsis, bacterial and viral infections and inflammatory diseases where LPS, LTA, viral envelope proteins, and/or heat shock proteins contribute to pathogenesis.

4G10, a Monoclonal Antibody Against the Chemokine Receptor CXCR4, Raised Against a Synthetic Peptide of 38 Residues in Length Derived From the N-terminal Sequence of CXCR4

Edward A. Berger and Christopher C. Broder (NIAID)

DHHS Reference No. E–340–2002/0

Licensing Contact: Sally Hu; 301/435–5606; *hus@od.nih.gov*

This invention identifies a monoclonal antibody (4G10) against the chemokine receptor CXCR4 and is a mouse IgG1 antibody. CXCR4 has been identified as a co-receptor mediating entry of HIV–1 into T cells. Subsequently, CXCR4 has been implicated in normal physiological functions, including activation of B cells and B cell progenitors and guiding their migration into the bone marrow (via its ligand SDF–1). CXCR4 also functions in T cell progenitor migration and neural progenitor stem cell activation. Since