DATES: July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Mark Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In FR Doc. 00–17944 appearing on page 44061 in the **Federal Register** of July 17, 2000, the following correction is made:

On page 44061, in the first column, under the **ADDRESSES** caption, after the second sentence, ''Persons with access to the Internet may submit electronic comments on the collection of information at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.'' is added.

Dated: July 21, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18942 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0930]

Request for Nominations for Working Groups Under the Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for qualified persons to serve on two fact-finding working groups being formed to support the Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science. The working groups will identify and report on scientific issues that may benefit from focused nonclinical research and collaboration.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees, and therefore, encourages nominations of qualified candidates from these groups. Final selections from among qualified candidates for each working group will be based on the expertise demonstrated for the specific focus areas and previous experience working in these areas.

DATES: All nominations should be received by September 29, 2000.

ADDRESSES: Please submit nominations to Docket No. 00N–0930, Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David C. Morley, Center for Drug Evaluation and Research (HFD–358), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5684, FAX 301–594–2503, e-mail: MORLEYD@CDER.FDA.GOV.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for qualified persons to serve on two fact-finding working groups being formed to support the Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science. The working groups will identify and report on scientific issues that may benefit from focused nonclinical research and collaboration.

FDA is forming the following two working groups:

- A multidisciplinary working group to identify promising areas of nonclinical scientific research to develop biomarkers and/or other evolving molecular technologies to identify or predict drug-induced cardiac tissue injury, and
- A multidisciplinary working group to identify promising areas of nonclinical scientific research to develop biomarkers and/or other evolving molecular technologies to identify or predict drug-induced vasculitis.

Criteria

Persons nominated for the working groups shall have exceptional accomplishments and expertise in the scientific fields appropriate to the working group. In particular, expertise in genomic and proteomic technologies is desired.

Nomination Procedures

Any interested person or organization may nominate one or more qualified persons for one or more of the working groups. Self-nominations are also accepted. Nominations should include appropriate biographical material, a brief (one-half page maximum) endorsement, a list of scientific publications relevant to the working group, and a statement that the nominee is aware of the nomination and is willing to serve on the working group if selected.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–18829 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1384]

Medical Devices; Draft Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves.'' Many foreign manufacturers and shippers of surgeons' and/or patient examination gloves have consistently failed to provide surgeons' and/or patient examination gloves of adequate quality for distribution in the United States, which presents a potential serious hazard to health for users and patients. The draft guidance is intended to help industry understand our policy to monitor continuously recidivist firms under our import program. This policy is neither final nor is it in effect at this time.

DATES: Submit written comments concerning this draft guidance by October 24, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves'' to the Division of Small Manufacturers 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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch, (HFA–305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rebecca K. Keenan, Center for Devices and Radiological Health (HFZ–333), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import surgeons' and patient exam gloves that violate quality requirements. FDA's experience with sampling, examination, and testing of surgeons' and/or patient examination gloves raises concerns about the barrier properties of some gloves exported to the United States. Our analyses of surgeons' and patient examination gloves exported to the United States show a significant variation in the quality of the gloves exported by various manufacturers/shippers. We repeatedly place the same manufacturers/shippers on import detention due to leaks and defects in their gloves. These firms then need to provide us with private laboratory analyses for a number of shipments in order to demonstrate that the quality of the gloves and the firm's manufacturing operations comply with FDA standards. Once the firms provide such evidence, we remove them from import alert. However, many of these same manufacturers/shippers have repeated violative analyses and return to import alert status. This cyclical problem of violations requires continuous auditing and monitoring of recidivist firms to prevent the entry of defective gloves into the United States.

In an attempt to ensure that surgeons' and/or patient examination gloves exported to the United States are in compliance with FDA's standards, we revised Import Alert #80–04, ''Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves,'' referred to as the ''recidivist policy.'' This initiative was a joint effort between the agency's Center for Devices and Radiological Health's Office of Compliance, ORA's Division of Import Operations and Policy, and the Office of Chief Counsel.

The recidivist policy defines three increasingly stringent compliance levels for firms who have shipped violative surgeons' and patient examination gloves to the United States. Levels 1 and 2 allow voluntary compliance opportunities, while Level 3 provides a mechanism to issue a warning letter for apparent violations of the Federal Food, Drug, and Cosmetic Act, including noncompliance with the quality systems regulation for good manufacturing practices. A finding of Level 3 noncompliance will automatically place any future shipments of surgeons' or patient examination gloves from the manufacturer/shipper on detention, without the need for FDA to perform an actual inspection at the manufacturer, due to the continued failure of the surgeons' and/or patient examination gloves to pass minimum FDA standards upon import.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a draft Level 1 guidance consistent with GGP's. This guidance document represents the agency's current thinking on the surveillance and detention without physical examination of surgeons' and/or patient examination gloves. 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 applicable statute, regulations, or both.

II. Electronic Access

In order to receive the draft guidance on ''Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1141 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. 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 access to the Internet. Updated on a regular basis, the CDRH home page includes various Level 1 guidance documents for comment, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance for Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves'' will be available at http://www.fda.gov/cdrh/oc/glove1.pdf.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by October 24, 2000. Two copies of any 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 draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 12, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–18830 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–437, 437A, 437B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to