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This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import surgeons' and patient exam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.

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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

be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Worksheet, Rehabilitation Unit Criteria Worksheet, and Rehabilitation Hospital Criteria Worksheet, and Supporting Regulations at 42 CFR 412.20–412.32; *Form No.:* HCFA–437, 437A, and 437B (OMB# 0938–0358); *Use:* The rehabilitation hospital/unit and psychiatric unit criteria worksheets are necessary to verify and reverify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system; *Frequency:* Annually; *Affected Public:* Business or other-for-profit, Not-for-profit institutions, State, local, or tribal government.; *Number of Respondents:* 2,580; *Total Annual Responses:* 2,580; *Total Annual Hours:* 645.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 11, 2000.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–18835 Filed 7–25–00; 8:45 am]

BILLING CODE 4120–03–P

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: The National Health Service Corps (NHSC) Scholarship Program In-School Worksheets (New)

The National Health Service Corps (NHSC) Scholarship Program was established to help alleviate the geographical and specialty maldistribution of physicians and other health practitioners in the United States. Under this program, health professional students are offered scholarships in return for services in a federally-designated Health Professional Shortage Area (HPSA). If awarded an NHSC Scholarship, the Program will require the schools and the awardees to review and complete relative data collection worksheets for each year that the student is NHSC Scholar.

The Data Sheet Form requests that the NHSC Scholar review the form for accuracy of pertinent information such as, social security number, contact information, current curriculum, and date of graduation information. If the scholar finds the printed information to be accurate, they must sign the form and return it to the NHSC Scholarship Program in the envelope provided. If the NHSC Scholar finds the information inaccurate in regards to their name or contact information, they are to make the necessary changes directly on the form. If the inaccurate information pertains to their curriculum or date of graduation, the scholar will make changes directly on the form and include written notification from their school.

The Verification Sheet Form is sent to the school along with a list of the NHSC scholars who are enrolled at their school for the current academic year. The schools are asked to verify and/or correct the enrollment status of each of the scholars on the list. Once the verification is complete the school must sign and date the form and return it to the NHSC Scholarship Program in the envelope provided.

The Contact Sheet Form is sent to the schools and it requests the contact information of pertinent school officials. This information is used by the NHSC Scholarship Program for future contacts with the schools.

The estimated burden is as follows:

Form name	Number of respondents	Responses per respondent	Hours per response (min)	Total burden hours
Data Sheet	800	1	10	137
Verification Sheet	800	1	10	137
Contact Sheet	800	1	10	137
Total	800	.....	.....	411