amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices.

C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is dependent totally on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements. (Note: Most pharmaceutical manufacturers already use a one-page modified version of the Form FDA 3500A where section G from the back of the form is substituted for section D on the front of the form.)

D. Medical Device Baseline Information

The Medical Device Reporting—Baseline form (Form FDA 3417) relates specifically to the individual device and must be submitted with the first adverse event on that device reported via Form FDA 3500A. The information collected includes the basis for marketing (510(k), PMA, etc.), product code for the device, common name, location where manufactured, and other identifying information. The Health Industry Manufacturers Association (HIMA) first commented in 1992 on the redundancy of information required for the Baseline form stating that the information is also collected by the agency through the device listing process (Form FDA 2892) and through Form FDA 3500A. In 1998, HIMA commented again and, at the request of OMB, FDA explored revising Form FDA 3500A to include the information required by the Baseline form that is not collected through the listing process.

In discussions with OMB it was decided that FDA would not attempt to revise Form FDA 3500A at this time, but would proceed with collecting the information required by the Baseline form as a separate part of the device listing process especially because some of the information required by the current Baseline form will be collected in that listing as a change in the listing regulations. Because the collection of registration and listing information will be through electronic means, the agency envisions a menu option on the Internet site to facilitate the collection of Baseline information.

FDA will be holding stakeholder meetings to discuss the new device registration and listing system and will discuss using the new device registration and listing system electronic process as the vehicle for the Baseline information collection at those meetings.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center(s) [1] (21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500 [2]	16,198	1	16,198	0.5	8,099
Form 3500A [3] (310.305, 314.80, 314.98, and 600.80)	600	455.2	273,109	1.0	273,109
CDRH					
Form 3500 [2]	2,650	1	2,650	0.5	1,325
Form 3500A [3] (part 803)	2,046	24	49,305	1.0	49,305
CFSAN					
Form 3500 [2]	550	1	550	0.5	275
Form 3500A [3] (No mandatory requirements)	0	0	0	1.0	0
Total Hours					332,113
Form 3500 [2]					9,699
Form 3500A [3]					332,414

[1] CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), CFSAN (Center for Food Safety and Applied Nutrition).
[2] FDA Form 3500 is for voluntary reporting,
[3] FDA Form 3500A is for mandatory reporting.
Note.—The figures shown in table 1 of this document are based on actual calendar year 1999 reports and respondents for each Center and type of report.

As more medical products are approved by FDA and marketed, and as knowledge increases regarding the importance of notifying FDA when adverse events and product problems are observed, it is expected that more reports will be submitted.

Dated: July 21, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18944 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–1373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting and Recordkeeping Requirements for Mammography Facilities; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 17, 2000 (65 FR 44061). The document announced an opportunity for public comment on information collection requirements for mammography facilities, standards, and lay summaries for patients. The document was published with an inadvertent error. This document corrects that error.

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