Application No.	Drug	Applicant
NDA 4–038	Diethylstilbestrol (DES) Injection.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 4–039	DES Tablets.	Do.
NDA 4–040	DES Suppository.	Do.
NDA 4–041	DES Tablets.	Do.
NDA 4–056	Stilbetin Tablets (Diethylstilbestrol Tablets USP).	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 6–327	Isuprel (Isoproterenol Hydrochloride) Inhalation Solution.	Sanofi-Synthelabo, Inc., 90 Park Ave., New York, NY 10016–1389.
NDA 7–371	Mecostrin Injection (Dimethyl Tubocurarine Chloride).	Bristol-Myers Squibb Co.
NDA 8–392	Nydrazid (Isoniazid USP) Tablets, Syrup, Capsules.	Do.
NDA 9–052	Rezipas (Aminosalicylic Acid Resin Powder).	Do.
NDA 9–273	Rauwolfia Serpentina, 50-milligram (mg) and 100-mg Tablets, 35-mg Capsule.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
NDA 9–627	Reserpine, 0.1-mg, 0.25-mg, 0.5-mg, and 1-mg Tablets.	Do.
NDA 10–010	Stilphostrol (Diethylstilbestrol Diphosphate) Injection and Tablets.	Bayer Corp., 400 Morgan Lane, West Haven, CT 06516–4175.
NDA 10–347	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 11–359	Ora-testryl (Fluoxymesterone Tablets USP).	Do.
NDA 11–642	Cardioquin (Quinidine Polygalacturonate) 275-mg Tablets.	Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850–3590.
NDA 11–745	Konakion (Phytonadione) Injection.	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 12–248	Plegine (Phendimetrazine Tartate) Tablets.	Wyeth Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 12–339	Bronkometer (Isoetharine Mesylate Inhalation Aerosol) and Bronkosol (Isoetharine Hydrochloride Inhalation Solution).	Sanofi-Synthelabo, Inc.
NDA 16–911	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 17–424	Septisol Foam (Hexachlorophene).	Steris Corp., P.O. Box 147, St. Louis, MO 63166–0147.
NDA 18–672	Nitro IV 5 mg/milliliters (mL) Injection and Nitronal Injection.	G. Pohl-Boskamp GmbH & Co., Kieler Strasse 11, D–25551 Hohenlockstedt, Germany.
NDA 18–762	Brethaire (Terbutaline Sulfate) Inhalation Aerosol.	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936–1080.
NDA 19–069	Mycelex (Clotrimazole) Vaginal Tablets.	Bayer Corp.
NDA 19–082	Dalgan (Dezocine) Injection, 5, 10, and 15 mg/mL.	AstraZeneca LP, 725 Chesterbrook Blvd., Wayne, PA 19087–5677.
NDA 19–174	Trandate HCT (Labetalol Hydrochloride/ Hydrochlorothiazide) Tablets.	Glaxo Wellcome, Inc., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 19–287	DIZAC (Diazepam Injectable Emulsion).	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 20–559	Tritec (Ranitidine Bismuth Citrate) Tablets.	Glaxo Wellcome, Inc.
NDA 21–048	17β-Estradiol Transdermal System.	R. W. Johnson Pharmaceutical Research Institute, 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869–0602.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 30, 2000.

Dated: September 5, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–23477–Filed 9–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1497]

Draft Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4.'' This draft guidance is neither final nor is it in effect at this time. The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The draft guidance document is intended to help facilities and their personnel meet the MQSA final regulations.

DATES: Submit written comments concerning this draft guidance by December 12, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4'' to the Division of Small

Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft 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 brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ 240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. In the **Federal Register** of October 28, 1997 (62 FR 55976), FDA published the MQSA final regulations. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993). Development of this guidance document began in December 1999.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. 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.

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 draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1159) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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 ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4,'' 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. ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4'' will be available at http://www.fda.gov/cdrh/mammography.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by December 12, 2000. Two copies of any comments are to be submitted, except that individual 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: August 29, 2000.

Linda S. Kahan,

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

[FR Doc. 00–23478 Filed 9–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4565–N–22]

Notice of Proposed Information Collection: Comment Request; Multifamily Coinsurance Claims Package, Section 223(f)

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting comments on the subject proposal.

DATES: *Comments due date:* November 13, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8100, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Steven A. Trojan, Systems Accountant, Office of Financial Services, 451 7th Street, SW., Washington, DC 20410, telephone (202) 401–2168, extension 2823 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility: (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information: (3) Enhance the quality, utility, and clarity of the information be collected; and (4) Minimize the burden of the collection of information on those are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.