<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 4–038</td>
<td>Diethylstilbestrol (DES) Injection.</td>
<td>Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.</td>
</tr>
<tr>
<td>NDA 4–039</td>
<td>DES Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 4–040</td>
<td>DES Suppository.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 4–041</td>
<td>DES Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 4–056</td>
<td>Stilbetin Tablets (Diethylstilbestrol Tablets USP).</td>
<td>Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.</td>
</tr>
<tr>
<td>NDA 7–371</td>
<td>Mecoeunin Injection (Dimethyl Tubucaracine Chloride).</td>
<td>Bristol-Myers Squibb Co.</td>
</tr>
<tr>
<td>NDA 8–392</td>
<td>Nydrazid (Isoniazid USP) Tablets, Syrup, Capsules.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 9–052</td>
<td>Rezipas (Aminosalicylic Acid Resin Powder).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 9–273</td>
<td>Rauwolfa Serpentina, 50-milligram (mg) and 100-mg Tablets, 35-mg Capsule.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 9–627</td>
<td>Reserpine, 0.1-mg, 0.25-mg, 0.5-mg, and 1-mg Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 10–010</td>
<td>Stilphosproc (Diethylstilbestrol Diphosphate) Injection and Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 10–347</td>
<td>Delalutin (Hydroxyprogesterone Caproate Injection USP).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 11–359</td>
<td>Ora-testy (Fluvoxymesterone Tablets USP).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 11–642</td>
<td>Cardioquin (Quinidine Polygalacturonate) 275-mg Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 11–745</td>
<td>Konakion (Phytndonaine) Injection.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 12–248</td>
<td>Pleine (Phendimetrazine Tarte) Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 12–339</td>
<td>Bronkometer (Isoetharine Mesylate Inhalation Aerosol) and Bronkosol (Isoetharine Hydrochloride Inhalation Solution).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 16–911</td>
<td>Delalutin (Hydroxyprogesterone Caproate Injection USP).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 17–424</td>
<td>Septisol Foam (Hexachlorophene).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 18–672</td>
<td>Nitro IV 5 mg/milliliters (mL) Injection and Nitronal Injection.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 18–762</td>
<td>Brethaire (Terbutaline Sulfate) Inhalation Aerosol.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 19–069</td>
<td>Mycelex (Clotrimazole) Vaginal Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 19–082</td>
<td>Dalgian (Dezocine) Injection, 5, 10, and 15 mg/mL.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 19–287</td>
<td>DIZAC (Diazepam Injectable Emulsion).</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 20–559</td>
<td>Tritic (Ranitidine Bismuth Citrate) Tablets.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 21–048</td>
<td>17β-Estradiol Transdermal System.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

**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

“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.


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

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 to respond;
including the use of appropriate
automated collection techniques or
other forms of information technology,
e.g., permitting electronic submission of
responses.