The fabricated data were not included in any publications.

Ms. Restrepo has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed, for the three (3) year period beginning December 7, 1998:

(1) To exclude herself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution that submits an application for PHS support for a research project on which her participation is proposed or which uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Ms. Restrepo's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 98–33405 Filed 12–16–98; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0339]

FDA Plan for Statutory Compliance; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of availability that appeared in the **Federal Register** of November 24, 1998 (63 FR 65000). The notice announced the availability of the ''FDA Plan for Statutory Compliance'' which was published in compliance with the Food and Drug Administration Modernization Act of 1997. The document was published with minor errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Steven H. Chasin, Office of Planning and Evaluation (HFP–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5207.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–31387 beginning on page 65000 in the **Federal Register** of Tuesday, November 24, 1998, the following corrections are made:

1. On page 65000, in the first column, in the second paragraph of the ''ADDRESSES'' section, in lines eight and nine, ''http://www.fda.gov/opacom/7modact'' is corrected to read ''http://www.fda.gov/opacom/7modact.html''.

2. On page 65039, in the table, under the ''Time frame'' column, under the subheading ''Non-PDUFA'', in line three, the phrase ''and PLA/BLA major supplements'' is removed.

3. On page 65039, in the table, under the ''Overdue'' column, in the 5th entry, ''(CBER)'' is removed; in the same table, in the same column, in the 6th entry ''142'' is added; in the 10th entry, ''52'' is added; and in the 11th entry, ''6'' is added.

4. On page 65039, in the third column following the table, in lines eight and nine, ''http://www.fda.gov/oc/fdama/fdamapln/appenda'' is corrected to read ''http://www.fda.gov/oc/fdama/fdamapln/appenda.htm''.

5. On page 65040, in the first column, in lines 12 and 13, ''http://www.fda.gov/oc/fdama/fdamapln/appendb'' is corrected to read ''http://www.fda.gov/oc/fdama/fdamapln/appendb.htm''; on that same page, in the second column, in lines 4 and 5, ''http://www.fda.gov/oc/fdama/fdamapln/appendc'' is corrected to read ''http://www.fda.gov/oc/fdama/fdamapln/appendc.htm''; and on that same page, in the same column, in lines 15 and 16, ''http://www.fda.gov/oc/fdama/fdamapln/appendd'' is corrected to read''http://www.fda.gov/oc/fdama/fdamapln/appendd.htm''.

Dated: December 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33353 Filed 12–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 78N–0280; DESI Nos. 740, 1543, and 7661]

Estrogens for Postpartum Breast Engorgement; Withdrawal of Approval of the Labeled Indication for Postpartum Breast Engorgement in Estrogen-Containing Drug Products; Final Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of estrogen-containing drugs insofar as they are indicated for use in postpartum breast engorgement. The basis for the action is that estrogens are not shown to be safe for that use.

EFFECTIVE DATE: December 17, 1998.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: For many years, estrogen-containing drug products were used to suppress postpartum breast engorgement. By the 1970's, however, the use of estrogens was shown to be associated with an increased risk of puerperal thromboembolism. Moreover, estrogen dosages for the suppression of postpartum breast engorgement were higher than for other labeled indications. The risk of thromboembolism was first evaluated by the FDA Obstetrics and Gynecology Advisory Committee, now called the Advisory Committee for Reproductive Health Drugs (the Committee), on July 15 and 16, 1976. At that time, the Committee recommended that estrogen drug products indicated for the suppression of postpartum breast engorgement contain an insert stating that the risk of thromboembolism should be considered in conjunction with the risk-free alternative of the use of breast binding and mild analgesics. On January 31, 1978, after additional risk evaluation, the Committee recommended that estrogen-containing drug products' indication for the suppression of postpartum breast engorgement be withdrawn.

In a notice of opportunity for hearing (NOOH) published in the **Federal Register** of October 24, 1978 (43 FR 49564), the agency proposed to