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

withdraw approval of all new drug applications (NDA's) for estrogen-containing drug products labeled for use in postpartum breast engorgement approved either before or after the Drug Amendments of 1962 (Pub. L. 87–781). The NOOH also applied to any identical, similar, or related drug product whether or not it was the subject of an NDA. The NOOH listed the following NDA's:

1. NDA 0–740; Di-Ovocylin Injection containing estradiol dipropionate; Ciba Pharmaceutical Co., Division Ciba Giegy Corp., 556 Morris Ave., Summit, NJ 07901.

2. NDA 4–039; Stilbestrol Ect. containing diethylstilbestrol; Eli Lilly & Co., Box 618, Indianapolis, IN 46206.

3. NDA 4–041; Stilbestrol Tablets and Injection containing diethylstilbestrol; Eli Lilly & Co.

4. NDA 4–056; Stilbestrol Tablets, Injection, and Suppositories containing diethylstilbestrol; E. R. Squibb & Sons, Inc., Box 4000, Princeton, NJ 08540.

5. NDA 4–073; Stilbestrol Perles, Injection and Suppositories containing diethylstilbestrol; The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.

6. NDA 4–782; Premarin Tablets containing conjugated estrogens; Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave., New York, NY 10017.

7. NDA 4–823; Estrone Injection containing estrone; Abbott Laboratories, 14th and Sheridan Rd., North Chicago, IL 60064.

8. NDA 5–159; Diethylstilbestrol Dipropionate Tablets containing diethylstilbestrol dipropionate; Blueline Laboratories, Inc., 302 South Broadway, St. Louis, MO 63102.

9. NDA 5–233; Diethylstilbestrol Tablets containing diethylstilbestrol; High Chemical Co., 1760 North Howard St., Philadelphia, PA 19122.

10. NDA 5–292; Estinyl Tablets containing ethinyl estradiol; Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.

11. NDA 7–661; AE Tablets and Tylosterone Tablets containing diethylstilbestrol and methyltestosterone; Eli Lilly & Co.

12. NDA 8–099; Tylosterone Injection containing diethylstilbestrol and methyltestosterone; Eli Lilly & Co.

13. NDA 8–102; Tace Tablets and Capsules containing chlorotrianisene; Merrell-National Laboratories, Division of Richardson-Merrell Inc., 110 East Amity Rd., Cincinnati, OH 45215.

14. NDA 8–579; Vallestril Tablets containing methallenestril; Searle Laboratories, Division of G. D. Searle & Co., Box 5100, Chicago, IL 60680.

15. NDA 9–402; Delestrogen Injection, Delestrogen 4X Injection, and Delestrogen 2X Injection containing estradiol valerate; E. R. Squibb & Sons, Inc.

16. NDA 9–545; Deladumone Injection containing testosterone enanthate and estradiol valerate; E. R. Squibb & Sons, Inc.

17. NDA 10–597; Tace-Androgen Capsules containing chlorotrianisene and methyltestosterone; Merrell-National Laboratories.

18. NDA 11–444; Tace Capsules containing chlorotrianisene and Tace with Ergonovine Capsules containing chlorotrianisene and ergonovine maleate; Merrell-National Laboratories.

19. NDA 16–235; Tace 72-Milligram Capsule containing chlorotrianisene; Merrell-National Laboratories.

20. NDA 16–768; Estrovis Tablets containing quinestrol; Warner Chilcott Laboratories, Division Warner Lambert Co., 201 Tabor Rd., Box W, Morris Plains, NJ 07950.

In response to the NOOH, Merrell-National Laboratories, Parke-Davis, E. R. Squibb & Sons, Inc., Byk-Gulden, Inc., and the American College of Obstetricians and Gynecologists (the College) requested hearings, but the firms voluntarily agreed to remove the indication from their labeling. Since then, the College and the firms, or their respective successors in interest, have withdrawn their hearing requests. (The approvals of NDA 7–661, NDA 8–099, and NDA 9–545 were withdrawn in a **Federal Register** notice of October 29, 1998 (63 FR 58053); the approval of NDA 10–597 was withdrawn in a **Federal Register** notice of June 25, 1993 (58 FR 34466); the approval of NDA 16–768 was withdrawn in a **Federal Register** notice of March 27, 1996 (61 FR 13506).)

Therefore, for reasons stated in the NOOH of October 24, 1978, as well as the reasons discussed above, the Director of the Center for Drug Evaluation and Research hereby withdraws approval of any estrogen-containing drug product insofar as it is labeled for the suppression of postpartum breast engorgement. (In the **Federal Register** of January 17, 1995 (60 FR 3404), FDA withdrew approval of bromocriptine mesylate for the indication of the prevention of physiological lactation, i.e., postpartum breast engorgement; today's action means, therefore, that no product is currently approved for this indication.) This notice is issued under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10(a)(1)) and redelegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: November 30, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–33455 Filed 12–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0227]

Determination of Regulatory Review Period for Purposes of Patent Extension; Silicone AMO® ARRAY® Multifocal IOL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Silicone AMO® ARRAY® multifocal IOL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical