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-Ovocyn Injection containing estradiol dipropionate; Ciba Pharmaceutical Co., Division Ciba Geigy 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.
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; Blueine Laboratories, Inc., 302 South Broadway, St. Louis, MO 63102.
9. NDA 5–233; Diethylstilbestrol Tablets containing diethylstilbestrol; Lederle Laboratories, 45th Street and Grand Avenue, New York, NY 11385.
10. NDA 5–292; Estinyl Tablets containing ethinyl estradiol; Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.
11. NDA 7–661; AE Tablets and Tylostrone Tablets containing diethylstilbestrol and methyltestosterone; Eli Lilly & Co.
12. NDA 8–099; Tylostrone 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; Vallesi Tablets containing methalenestrol; 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.

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).


Janet Woodcock,
Director, Center for Drug Evaluation and Research.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration

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
investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Silicone AMO® ARRAY® multifocal IOL. Silicone AMO® ARRAY® multifocal IOL is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading aid and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Silicone AMO® ARRAY® multifocal IOL (U.S. Patent No. 4,898,461) from Vision Pharmaceuticals, L.P., and the Patent and Trademark Office requested that FDA determine the device’s regulatory review period. Shortly thereafter, the Patent and Trademark Office advised the Patent and Trademark Office that medical device, food additive, or color additives.) Petitions should be in the format specified in 21 CFR 10.30.

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 investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any...