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

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 FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 19, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Silicone AMO® ARRAY® multifocal IOL represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Silicone AMO® ARRAY® multifocal IOL is 2,846 days. Of this time, 2,478 days occurred during the testing phase of the regulatory review period, while 368 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 22, 1989. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on June 15, 1989. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on November 22, 1989, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: September 3, 1996. The applicant claims August 30, 1996, as the date the premarket approval application (PMA) for Silicone AMO® ARRAY® multifocal IOL (PMA P960028) was initially submitted. However, FDA records indicate that PMA P960028 was submitted on September 3, 1996.

3. *The date the application was approved*: September 5, 1997. FDA has verified the applicant's claim that PMA P960028 was approved on September 5, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,533 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 16, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 15, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–33453 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–0849]

Determination of Regulatory Review Period for Purposes of Patent Extension; Vitreon®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Vitreon® 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