B. Smith, Office on Disability and Health, National Center for Environmental Health, CDC, 4770 Buford Highway, Building 101, Mailstop F–29, Atlanta, Georgia 30341, telephone (770) 488–7082. (Internet address: jos4@cdc.gov). Epidemiologic and research-related technical assistance is available from Donald J. Lollar, Ed.D. at the same address, telephone (770) 488–7094. (Internet address: dcl5@cdc.gov).

For Part 2 applications, program assistance may be obtained from Douglas R. Browne, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, Building 101, Mailstop F–41, Atlanta, Georgia 30341, telephone (770) 488–4031. Internet address: drb7@cdc.gov. Epidemiologic and research-related technical assistance is available from Joe Sniezek, M.D., M.P.H. at the same address and telephone number. Internet address: jes6@cdc.gov. A packet of background information for Part 2 is available by contacting the above listed CDC staff.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report; Stock number 017–001–00474–0) or ''Healthy People 2000'' (Summary Report; Stock number 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: March 7, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–6489 Filed 3–13–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 97N–0036]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding the Cosmetic Product Voluntary Reporting Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 23, 1996 (61 FR 67556), the agency announced that the proposed information collection had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the information collection and assigned OMB control number 0910–0030. The approval expires on January 31, 2000. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6524 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0497]

I. D. Russell Co. Laboratories; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by I. D. Russell Co. Laboratories. The NADA provides for use of 10 percent sulfaquinoxaline powder for making animal feed and 20 percent sulfaquinoxaline liquid. The sponsor requested the withdrawal of approval because the products are no longer being marketed.

EFFECTIVE DATE: March 24, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501, is the sponsor of NADA 6–776, which provides for use of 10 percent sulfaquinoxaline powder for feed and 20 percent sulfaquinoxaline liquid. I. D. Russell Co. Laboratories requested that FDA withdraw approval of NADA 6–776 because the products are no longer being marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 6–776 and all supplements and amendments thereto is hereby withdrawn, effective March 24, 1997.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–6474 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 95P–0061, 95S–0117, 95S–0126, and 95S–0135]

Expiration Dates for Patents Extended by the Uruguay Round Agreements Act; Submission by Applicants of New Drug and New Animal Drug Applications; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a notice published in the Federal Register of July 21, 1995 (60 FR 37652), which announced the agency's position on patent information submitted by applicants of new drug applications (NDA's) and new animal drug applications (NADA's). On April 4, 1996, the U.S. Court of Appeals for the Federal Circuit issued a decision establishing the correct method for calculating patent term expiration dates for certain patents that are subject to both the Uruguay Round Agreements Act (URAA) and the patent term extension provisions of the U.S. Code. All NDA and NADA applicants should calculate patent term expiration dates in conformance with the court's decision and submit corrected patent term expiration dates to the agency.

DATES: NDA and NADA applicants that have already submitted patent term expiration dates should submit patent term expiration dates calculated in accordance with this notice by April 14, 1997.

ADDRESSES: Two copies of amended patent information pertaining to human drug products regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by the Center for Drug Evaluation and Research (CDER) should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by the Center for Biologics

Evaluation and Research (CBER) should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

A third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Division of Database Management, Drug Information Services Branch (HFD–85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 218, Rockville, MD 20852.

Two copies of amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the July 21, 1995, notice, which announced the agency's position on patent information submitted by applicants of NDA's and NADA's. In that notice, FDA stated that patent term expiration dates for certain patents that are subject to both the URAA and the patent term extension provisions of Title II of the Drug Price Competition and Patent Term Restoration Act and Title II of the Generic Animal Drug and Patent Term Restoration Act, both codified at 35 U.S.C. 156, should be calculated in accordance with the Patent and Trademark Office's determination (PTO determination) published in the Federal Register of June 7, 1995 (60 FR 30069). FDA also announced that it would not publish dates in ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book) or the ''FDA Approved Animal Drug Products'' (the Green Book) that the NDA or NADA applicant stated were not in accordance with the PTO determination.

The PTO determination and the July 21, 1995, notice were challenged in Federal court by a number of pharmaceutical companies that hold NDA's or NADA's. On April 4, 1996, the U.S. Court of Appeals for the Federal Circuit issued a decision in *Merck & Co.* v. *Kessler*, 80 F.3d 1543 (Fed. Cir. 1996) establishing the correct method for calculating patent expiration dates for patents subject to both patent extension under the URAA and the patent term extension provisions of 35 U.S.C. 156. The Federal Circuit remanded the case to the U.S. District Court for the Eastern District of Virginia, which issued orders that, among other things, established the patent expiration dates for the patents at issue in the litigation. (*Merck & Co.* v. *Kessler*, Civ. No. 95–1005–A (E.D. Va. Sept. 5, 1996); and *Organon, Inc.* v. *Kessler*, Civ. No. 95–1380–A (E.D. Va. Sept. 13, 1996).)

In conformance with the district court order, FDA is publishing the patent expiration dates determined in the order for the patents directly at issue in the litigation in the monthly supplement to the Orange Book. FDA advises that NDA and NADA applicants should submit to FDA within 30 days, new patent expiration dates calculated in accordance with the courts' orders for any patents that have already been submitted to FDA. Patent expiration dates already submitted to the agency that were calculated by the method described in the court's order need not be resubmitted. Expiration dates for patents first submitted to FDA after the date of this notice must be calculated in accordance with the method described in *Merck & Co.* v. *Kessler*.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CDER should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CBER should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

To expedite the availability to the public of the updated patent information, a third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Division of Database Management, Drug Information Services Branch (HFD–85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 218, Rockville, MD 20852.

Two copies of amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6413 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0051]

Eurexpan Labo; Premarket Approval of ContaClair® Multi-Purpose Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by the law firm of Akin, Gump, Strauss, Hauer and Field, as the United States Representative on behalf of Eurexpan Labo, 41120 Cellettes, France, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of ContaClair® Multi-Purpose Solution. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by April 14, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On December 19, 1991, the law firm of Akin, Gump, Strauss, Hauer and Field, as the United States Representative on behalf of Eurexpan Labo, 41120 Cellettes, France, submitted to CDRH an application for premarket approval of ContaClair® Multi-Purpose Solution. The device is a cleaning, rinsing, disinfecting, and storing solution and is indicated for cleaning, rinsing, disinfecting, and storing daily and extended wear clear and tinted soft (hydrophilic) contact lenses.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory