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

committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On June 20, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 14, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 16, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–6409 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97N–0083]

Abbreviated New Drug Applications; Positron Emission Tomography Radiopharmaceuticals; Notice of a Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to provide information to the positron emission tomography (PET) radiopharmaceutical industry on submitting abbreviated new drug applications (ANDA's) and other regulatory issues affecting PET radiopharmaceutical drug products. The workshop will provide guidance on topics such as ANDA regulatory requirements, registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, and labeling. An agenda and materials to be discussed at the workshop will be available before the workshop.

DATES: The workshop will be held on Monday, April 28, 1997, from 8 a.m. to 5 p.m. Because space is limited, interested persons are encouraged to register as soon as possible. Preregistration will be accepted through April 18, 1997. There is no registration fee for the workshop. The administrative docket will remain open until June 27, 1997, to receive written comments, data, information, or views on the workshop and materials distributed at the workshop.

ADDRESSES: The workshop will be held at the Parklawn Bldg., 5600 Fishers Lane, conference rm. D, Rockville, MD 20857. Persons interested in attending should pre-register by faxing their name, title, organization name if any, address, telephone and fax numbers to the contact person. Registrants' fax numbers should be provided, so that registration can be confirmed by return fax.

Before the workshop, the agenda and materials to be discussed at the workshop will be available via the Internet using the World Wide Web (WWW). To connect to the Center for Drug Evaluation and Research (CDER) Home Page, type http://www.fda.gov/cder and go to the ''What's Happening'' section. A transcript of the workshop will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 business days after the workshop at a cost of 10 cents per page.

Written comments on the workshop or materials discussed at the workshop can be submitted until June 27, 1997, to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this notice. Received comments may be viewed at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Susan C. Lange, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–160), 5600 Fishers Lane, Rockville, MD 20857, 301–443–0260, FAX 301–594–0746.

SUPPLEMENTARY INFORMATION:

I. Background

PET is a diagnostic imaging modality consisting of onsite production of radionuclides that are usually intravenously injected into patients for diagnostic purposes. The potential usefulness of a PET radiopharmaceutical is based upon the product's interaction with a biochemical process in the body.

Over the last 20 years, there has been increasingly widespread commercial use of a growing number of PET radiopharmaceuticals. Having considered the available information, including that presented to the agency at a March 1993 hearing and in written materials, in the Federal Register of February 27, 1995 (60 FR 10593), FDA provided additional notice and guidance to the industry stating how the agency would apply its regulatory authority to PET drug products.

Since the approval of one new drug application for F–18 FDG, PET drug product manufacturers have sought information on the submission of ANDA's. Details of the ANDA submission process will be discussed at the workshop. Other topics to be addressed include registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, labeling, and compliance with current