TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN 10/14/96 AND 10/25/96—Continued

Acquiring person/acquired person/acquired entity	PMN No.	Date terminated
Alliance Phamaceutical Corp. Henry L. Hillman, MDV Technologies, Inc	97–0179	10/25/96
Rush Presbyterian—St. Luke's Medical Center, Riverside Health System, Riverside Health System	97–0187	10/25/96
The Beacon Group III—Focus Value Fund, L.P., Berwind Group Partners, Micorpore Inc	97–0188	10/25/96
Aker ASA, Kjell Inge Rokke, RGI (Norway) AS	97–0189	10/25/96

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–29024 Filed 11–15–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0308]

Countrymark Cooperative, Inc.; 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 Countrymark Cooperative, Inc. The NADA provides for the use of tylosin Type A medicated articles to make Type C medicated feeds. Countrymark Cooperative requested the withdrawal of approval of the NADA because they are no longer making Type A medicated articles for use in Type C medicated feeds. In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the regulations by removing those entries which reflect approval of the NADA.

EFFECTIVE DATE: November 29, 1996.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: Countrymark Cooperative, Inc., 950 North Meridian St., Indianapolis, IN 46204–3909 (formerly the Indiana Farm Bureau Cooperative Association, Inc., 120 East Market St., Indianapolis, IN 46204), has voluntarily requested withdrawal of approval of NADA 125–226 that provides for use of tylosin Type A medicated articles to make tylosin Type C medicated swine feeds.

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 125–226, and all supplements and amendments thereto is hereby withdrawn, effective November 29, 1996.

In a final rule published elsewhere in this issue of the Federal Register, FDA is amending 21 CFR 510.600 and 558.625 to reflect withdrawal of approval of this NADA.

Dated: October 18, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–29390 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0425]

Paclitaxel Drug Products; Environmental Information Needed in New Drug Applications, Abbreviated New Drug Applications, and Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to clarify the environmental information that must be submitted to the Center for Drug Evaluation and Research (CDER) for drug products containing paclitaxel. Paclitaxel is an active moiety that may be obtained or derived from various wild or cultivated species of yews. Under the National Environmental Policy Act (NEPA), all Federal agencies are required to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. This action is being taken to ensure that environmental factors regarding paclitaxel drug products are adequately assessed.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5721.

SUPPLEMENTARY INFORMATION:

I. Background

NEPA requires all Federal agencies to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental impacts of approving drug product applications as an integral part of its regulatory process. FDA's regulations in 21 CFR part 25 specify that environmental assessments (EA's) or abbreviated environmental assessments (AEA's) must be submitted as part of NDA's, antibiotic drug applications, ANDA's, AADA's, IND's, and for other various actions described under § 25.22, unless the action qualifies for a categorical exclusion under §§ 25.23 and 25.24. FDA's regulations at § 25.23(c) provide that a person submitting an application for an action that falls within a class that qualifies for a categorical exclusion shall specify the provision that excludes the action from the requirement for an EA. FDA may require an applicant to provide information that establishes to the agency's satisfaction that the action requested is included within an excluded category and meets the criteria for the applicable exclusion (§ 25.23(c)). FDA will require an EA for any specific action that ordinarily is excluded if the agency has sufficient evidence to establish that the specific proposed action may significantly affect the quality of the human environment (§ 25.23(b)). In the Federal Register of January 11, 1996 (61 FR 1031), FDA announced the availability of a CDER guidance document entitled ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements'' (Guidance for Industry). The document was intended to provide guidance on how to prepare EA's for submission to

CDER in NDA's, antibiotic drug applications, ANDA's, AADA's, and IND's.

II. Paclitaxel Drug Products

The following clarifies the environmental information that must be submitted to CDER for drug products containing paclitaxel. For the purposes of the following discussion, ''applications'' is defined as IND's that are expected to enroll cumulatively 200 or more subjects, NDA's, and ANDA's.

In accordance with FDA's NEPA regulations (21 CFR part 25) and the Guidance for Industry, a person who submits an NDA, ANDA, or IND involving drug products containing paclitaxel shall include an EA for the requested action in the applicable format, unless the action qualifies for a categorical exclusion under §§ 25.23 and 25.24. In accordance with § 25.23(c), FDA will require those persons submitting applications involving drug products containing paclitaxel derived from natural sources to identify the sources of paclitaxel so that FDA can determine whether an EA is required.

FDA will treat all applications involving paclitaxel derived from or otherwise involving Pacific yew trees (Taxus brevifolia) as requiring the preparation of EA's. Accordingly, FDA will require persons to prepare and submit to the FDA EA's for applications involving paclitaxel derived from or otherwise involving the Pacific yew. The EA's shall, among other things, identify all sources of Pacific yew which are expected to be harvested in connection with the manufacture of paclitaxel relating to the application. The EA's shall, among other things, include a discussion of the anticipated environmental impacts of such harvests, measures that may be taken to mitigate adverse impacts, and reasonable alternatives. See in particular, format items 4, 9, 10 and 11, at § 25.31a. If the harvest took place prior to the issuance of this Federal Register notice, the EA's shall discuss, among other things, each such matter including mitigation measures that are still available. FDA will require this information in all future applications involving paclitaxel derived from or otherwise involving the Pacific yew and for all such applications which have not been finally acted upon by FDA by November 18, 1976.

FDA will subject such EA's to the NEPA process, and will complete and issue an EA and finding of no significant impact (FONSI) in accordance with §§ 25.32 and 25.42, or an environmental impact statement (EIS) and record of decision (ROD) in accordance with §§ 25.34 and 25.42, as required by NEPA, before approving any NDA or ANDA involving paclitaxel derived from or otherwise involving the Pacific yew tree. FDA will also subject such EA's for IND's involving paclitaxel derived from or otherwise involving the Pacific yew to the NEPA process, provided that in cases in which the IND involves treatment of subjects with serious or life-threatening disease, as determined by the FDA, the FDA, where NEPA permits, will not place the IND on clinical hold pending the completion of environmental documentation required by NEPA.

FDA is committed to assuring that assessment of environmental factors continues throughout the planning process and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values (§ 25.10). As provided by FDA regulations under § 25.22(b), ''Failure to submit an adequate EA, if one is required, . . . is sufficient grounds for FDA to refuse to file or approve the application or petition.''

EA's, FONSI's, EIS's and ROD's for drug products containing paclitaxel and other pertinent environmental information relating to approvals of drug products containing paclitaxel will be filed in Docket No. 92N–0489. This docket was previously established as a repository of environmental information relating to the first approval of a paclitaxel drug product (Taxol, NDA 20–262).

Dated: November 12, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–29486 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0423]

Dade Intl., Inc.; Premarket Approval of the aca® plus PSA Test Kit, aca® plus PSA Calibrator, and aca® plus PSA Control

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Dade Intl., Inc., Newark, DE, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the aca® plus PSA Test Kit, aca® plus PSA Calibrator, and aca® plus PSA Control. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 9, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 18, 1996.

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: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On February 1, 1996, Dade Intl., Inc., Newark, DE 19714, submitted to CDRH an application for premarket approval of the aca® plus PSA Test Kit, aca® plus PSA Calibrator, and aca® plus PSA Control. The device is a Prostate Specific Antigen (PSA) Test Kit, which consists of the PSA test pack and reaction vessel used in the aca® plus immunoassay system to quantitatively measure PSA in human serum. Measurements of PSA are used as an aid in the management of prostate cancer patients.

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 Immunology Advisory 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 September 9, 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