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

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 December 18, 1996, 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–29487 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0424]

Spine-Tech, Inc.; Premarket Approval of BAK™ Interbody Fusion System With Instrumentation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Spine-Tech, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BAK™ Interbody Fusion System with instrumentation. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 20, 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: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION: On August 28, 1995, Spine-Tech, Inc., Minneapolis, MN 55439–2029, submitted to CDRH an application for premarket approval of the BAK™ Interbody Fusion System with instrumentation. This device is an intervertebral body fusion device. It is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2–S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had 6 months of nonoperative treatment.

On May 23, 1996, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 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 (21 U.S.C. 360e(d)(3)) 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 December 18, 1996, 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–29394 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F