Wisconsin

Jeff Smith, Section Chief, State/Federal Relations, Wisconsin Department of Administration, 101 East Wilson Street—6th Floor, P.O. Box 7868, Madison, Wisconsin 53707; Telephone: (608) 266–0267, FAX: (608) 267–6931

Wyoming

Matthew Jones, State Single Point of Contact, Office of the Governor, 200 West 24th Street, State Capitol, Room 124, Cheyenne, Wyoming 82002; Telephone: (307) 777–7446, FAX: (307) 631–3909

Territories

Guam

Mr. Giovanni T. Sgambelluri, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910; Telephone: 011–671–472–2825

Puerto Rico

Norma Burgos/Jose E. Caro, Chairwoman/Director, Puerto Rico Planning Board, Federal Proposals Review Office, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–1119; Telephone: (809) 723–4444, FAX: (809) 724–3270, (809) 724–3103

North Mariana Islands

Mr. Alvaro A. Santos, Executive Officer, State Single Point of Contact, Office of Management and Budget, Office of the Governor, Saipan, MP, Northern Mariana Islands 96950; Telephone: (670) 664–2289, FAX: (670) 644–2272

Virgin Islands

Nelson Bowry, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802.

Please direct all questions and correspondence about intergovernmental review to: Linda Clarke, Telephone: (809) 774–0750, FAX: (809) 776–0069.

In accordance with Executive Order #12372, ''Intergovernmental Review of Federal Programs,'' this listing represents the designated State Single Points of Contact. The jurisdictions not listed no longer participate in the process but grant applicants are still eligible to apply for the grant even if your state, territory, commonwealth, etc. does not have a ''State single point of contact.'' States without ''State single point of contact'' include: Alabama, Alaska, American Samoa, Colorado, Connecticut, Kansas, Hawaii, Idaho, Louisiana, Massachusetts, Palau, Minnesota, Montana, Nebraska, New Jersey, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, and Washington. This list is based on the most current information provided by the States. Information on any changes or apparent errors should be provided to the Office of Management and Budget and the State in question. Changes to the list will only be made upon formal question. Changes to the list will only be made upon formal notification by the State. Also, this listing is published biannually in the Catalogue of Federal Domestic Assistance.

[FR Doc. 97–16935 Filed 6–27–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0254]

Cytyc Corp. Premarket Approval Of ThinPrep® 2000 Processor

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cytyc Corp., Marlborough, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the ThinPrep® 2000 System. After reviewing the recommendation of the Hematology and Pathology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by July 30, 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: 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 November 22, 1995, Cytyc Corp., Marlborough, MA 01752, submitted to CDRH an application for premarket approval of the ThinPrep® 2000 System. The device is an automated cytology slide preparation instrument and is intended as a replacement for the conventional method of pap smear preparation for use in screening for the presence of atypical cells, cervical cancer, or its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), as well as all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

On June 7, 1993, the Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. Cytyc Corp. withdrew the application and subsequently resubmitted the application on November 22, 1995.

On May 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 July 30, 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: June 5, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–17065 Filed 6–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0257]

Personal Health & Hygiene, Inc.; Premarket Approval of Dr. Brown's Home Drug Testing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Personal Health & Hygiene, Inc., Silver Spring, MD, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Dr. Brown's Home Drug Testing System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 21, 1997, of the approval of the application.

DATES: Petitions for administrative review by July 30, 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: Steven I. Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION: On December 19, 1995, Personal Health & Hygiene, Inc., Silver Spring, MD 20910, submitted to CDRH an application for premarket approval of Dr. Brown's Home Drug Testing System. Dr. Brown's Home Drug Testing System is an over-the-counter collection and transport system intended for use by individuals wishing to anonymously test urine samples for drugs of abuse (marijuana, cocaine, amphetamine, methamphetamine, phencyclidine (PCP), codeine, and morphine).

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 Clinical Chemistry and Toxicology 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 January 21, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director, Clinical and Review Policy, 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 July 30, 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: June 10, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–17064 Filed 6–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97M–0252]

Sulzer Orthopedics®, Inc.; Premarket Approval of the Natural Knee and Natural Knee® II with Cancellous Structured Titanium (CSTi™)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Sulzer Orthopedics®, Inc., Austin, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Natural Knee® and Natural Knee® II with Cancellous Structured Titanium (CSTi™). 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 March 21, 1997, of the approval of the application.

DATES: Petitions for administrative review by July 30, 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: Erin I. Keith, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.