whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated August 26, 1996 (Docket No. 96P–0316/CP), submitted in accordance with 21 CFR 314.122, Clausen & Associates, Inc., requested that the agency determine whether minocycline hydrochloride tablets were withdrawn from sale for reasons of safety or effectiveness. Minocycline hydrochloride (Minocin) tablets are the subject of approved NDA 50–451 held by Lederle Laboratories. In 1996, Lederle withdrew minocycline hydrochloride tablets from sale.

FDA has reviewed its records and, under § 314.161, has determined that minocycline hydrochloride tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain minocycline hydrochloride tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to minocycline hydrochloride tablets may be approved by the agency.

Dated: January 20, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–1849 Filed 1–26–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98M–0036]**

### Xytronyx, Inc.; Premarket Approval of the Periogard Periodontal Tissue Monitor

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Xytronyx, Inc., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Periogard Periodontal Tissue Monitor (PTM). After reviewing the recommendation of the Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 23, 1997, of the approval of the application.

**DATES:** Petitions for administrative review by February 26, 1998.

**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:** Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243.

**SUPPLEMENTARY INFORMATION:** On September 19, 1996, Xytronyx, Inc., San Diego, CA 92121, submitted to CDRH an application for premarket approval of the PTM. The device is a visual, periodontal test kit and is indicated for use as a rapid, chair-side, visual test for the qualitative determination of aspartate aminotransferase (AST) in gingival crevicular fluid. The PTM kit detects elevated levels of AST associated with tissue necrosis. It is intended to be used as an objective, biochemical adjunct to traditional methods of monitoring patients to assist in the decision to apply treatment and in the evaluation of treatment effectiveness.

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 Dental Products Panel and/or the Clinical Chemistry and Toxicology Devices Panel of the Medical Devices Advisory Committee, FDA advisory committees, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by the panel. On June 23, 1997, 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 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 February 26, 1998, 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 31, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 98–1942 Filed 1–26–98; 8:45 am]

**BILLING CODE 4160–01–F**