With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Institutional Review Boards—(21 CFR Part 56.115)—(OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, IRB's are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: (1) Written procedures describing the structure and membership of the IRB and the methods which the IRB will use in performing its functions; (2) the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; (3) minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; (4) records of continuing review activities; (5) copies of all correspondence between investigators and the IRB; (6) statements of significant new findings provided to subjects of the research; (7) and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by the FDA in conducting audit inspections of IRB's to determine whether IRB's and clinical investigators are providing adequate protections to human subjects participating in clinical research.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,000	14.6	10,000	65	131,400

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRB's review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one for purposes of estimating the burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRB's in its inventory. The 2,000 IRB's meet on an average of 14.6 times annually. The mean number of IRB meetings per year was derived from a study conducted by the agency and published by the Office of Planning and Evaluation. The agency estimates that approximately 4.5 hours of person time per meeting are required to transcribe and type the minutes of the meeting, to maintain records of continuing review activities, copies of all correspondence between the IRB and investigators, member records, and written IRB procedures which are approximately five pages per IRB.

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1944 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96P–0316]

Determination That Minocycline Hydrochloride Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that minocycline hydrochloride tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for minocycline hydrochloride tablets.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to

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]

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