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 (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 15, 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: October 17, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97–30029 Filed 11–13–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97M–0458]**

### NeuroControl, Corp.; Premarket Approval of Freehand System

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application submitted by NeuroControl, Corp., Cleveland, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Freehand System . After reviewing the recommendation of the Neurological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 15, 1997, of the approval of the application.

**DATES:** Petitions for administrative review by December 15, 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:** Levering G. Keely, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

**SUPPLEMENTARY INFORMATION:** On June 17, 1996, NeuroControl Corp., Cleveland, OH 44106, submitted to CDRH an application for premarket approval of the Freehand System . The system includes: Implantable receiver-stimulator Model 202–1, implantable epimysial electrode set Model 203–1, surgical electrode positioning kit Model 207–1, patient external system Model 204–1, and programming system Model 209–1. The system is an upper extremity neuroprosthesis and is intended to improve a patient's ability to grasp, hold, and release objects. The system is indicated for use in patients who: (1) Are tetraplegic due to C5 or C6 spinal cord injury (ASIA Classification), (2) have adequate functional range of motion of the upper extremity, (3) have intact lower motor neuron innervation of the forearm and hand musculature, and (4) are skeletally mature.

On September 25, 1996, the Neurological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August 15, 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 (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 15, 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: October 16, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97–30030 Filed 11–13–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Psychopharmacologic Drugs Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA regulatory issues.

*Date and Time*: The meeting will be held on December 4, 1997, 8:30 a.m to 5 p.m.

*Location*: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person*: Rhonda W. Stover, or Robinette Taylor, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On December 4, 1997, the committee will hear presentations from the Institute of Medicine on the marketed product Halcion® (triazolam, Pharmacia and Upjohn Co.).

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 10, 1997.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 97–30034 Filed 11–13–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

*Proposed Project:* The Health Education Assistance Loan (HEAL)

*Program:* Application Form—0915–0038—Extension, No Change. The Health Education Assistance Loan (HEAL) program provides federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, make HEAL loans which are insured by the Federal Government against loss due to borrowers' death, disability, bankruptcy, and default. The basic purpose of the program is to assure the availability of funds for loans to eligible students who need to borrow money to pay for their educational costs.

The HEAL program is being phased out and no new loans will be made after September 30, 1998, unless reauthorization is enacted. We are, however, requesting a 3-year extension of the OMB approval of the HEAL Application Form HRSA–700 because lenders will continue to use this form for consolidation loans through fiscal year (FY) 2000. Students use the application to apply for HEAL loans (through FY 1998) and consolidation of loans, schools use the application to determine a student's eligibility and maximum approval amount of each loan (through FY 1998 only), and lenders use the application to determine student eligibility and the amount of the installment or disbursement to be given to the borrower, and to process consolidation loans.

The estimate of burden for the application form for FY 1998 is as follows:

| Type of respondent | Number of respondents | Responses per respondent | Total number of responses | Burden per response (minutes) | Total burden hours |
|---|---|---|---|---|---|
| Applicants | 8,230 | 1 | 8,230 | 25 | 3,429 |
| Schools | 190 | 41 | 7,730 | 32 | 4,123 |
| Lenders | 11 | 748 | 8,230 | 35 | 4,801 |
| Total | 8,431 | ..... | 24,190 | ..... | 12,353 |

The estimate of burden for the application form for FY 1999 and 2000 (for consolidation loans only) is as follows: