number. OMB has now approved the information collection and has assigned OMB control number 0910–0433. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8612 Filed 4–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1976N–0151 and 1977N–0203]

Isocarboxazid; Drugs for Human Use; Drug Efficacy Study Implementation; Revocation of Exemption; Announcement of Marketing Conditions; Followup Notice; and Opportunity for Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the temporary exemption that has allowed isocarboxazid products to remain on the market beyond the time limits scheduled for implementation of the Drug Efficacy Study. FDA announces the conditions for marketing this product for the indication now regarded as effective. Isocarboxazid, a monoamine oxidase inhibitor, is used in the treatment of depression.

DATES: The revocation of exemption is effective April 16, 2004. Requests for hearing are due by May 17, 2004; information to justify a hearing is due by June 15, 2004.

ADDRESSES: Communications in response to this document are to be identified with reference number Drug Efficacy Study Implementation (DESI) 11961, and directed to the attention of the appropriate office listed in the following paragraphs.

Original abbreviated new drug applications (ANDAs): Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Requests for hearing: (identify with docket numbers found in the heading of this document): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Requests for opinion of the applicability of this document to a specific product: Division of New Drugs and Labeling Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION:

I. Background

The following new drug application (NDA) is the subject of this document:

NDA 11–961; MARPLAN Tablets containing isocarboxazid, 10 milligrams (mg); Oxford Pharmaceutical Services, Inc., One U.S. Highway 46 West, Totowa, NJ 07512 (formerly held by Roche Laboratories (Roche), Division of Hoffman-LaRoche, Inc., Nutley, NJ 07110).

In a document published in the **Federal Register** of July 9, 1966 (31 FR 9426), all holders of NDAs that became effective before October 10, 1962, on the basis of a showing of safety, were requested to submit to FDA reports containing the best data available in support of the effectiveness of their products for the claimed indications. Roche, then the holder of NDA 11–961, did not submit data on MARPLAN. Consequently, MARPLAN was not included in the initial phase of the DESI review, that is, the review conducted by the National Academy of Sciences-National Research Council. Nevertheless, FDA reviewed available information on MARPLAN, including information subsequently submitted by Roche, and concluded that substantial evidence of effectiveness of the drug was lacking. Accordingly, in the **Federal Register** of October 5, 1976 (41 FR 43938), the agency issued a notice of opportunity for hearing (NOOH) on a proposal to withdraw approval of NDA 11–961 for MARPLAN Tablets.

In response to the October 1976 document, Roche submitted evidence to document a medical need for MARPLAN and indicated it was making arrangements to conduct the necessary studies to determine the effectiveness of the drug.

In a document published in the **Federal Register** of July 14, 1978 (43 FR 30351), FDA temporarily exempted isocarboxazid from the time limits established for completing the DESI program (paragraph XIV, category XX exemption). The exemption allowed the drug to remain on the market pending completion and review of additional clinical studies to determine its effectiveness. The July 1978 exemption document established conditions for marketing isocarboxazid, including a requirement that the drug be labeled as probably effective for severe reactive or endogenous depression. That document also required ANDAs for duplicate products covered by the exemption and established a schedule for the submission of protocols, and for the initiation and completion of studies. Accordingly, in the same issue of the **Federal Register** (43 FR 30350), FDA published a document rescinding the 1976 NOOH for MARPLAN.

In a **Federal Register** document of August 28, 1979 (44 FR 50409), FDA amended the previously published conditions for marketing isocarboxazid specified in the July 1978 exemption document (43 FR 30351). The amended conditions required that isocarboxazid be labeled as probably effective for the treatment of depressed patients who are refractory to tricyclic antidepressants or electroconvulsive therapy and depressed patients in whom tricyclic antidepressants are contraindicated. The August 1979 document also extended the time limits for submitting protocols and for completing studies on isocarboxazid.

On the basis of the agency's review of additional data and information submitted by the holder of NDA 11–961, the Director of the Center for Drug Evaluation and Research (CDER) has determined that isocarboxazid (MARPLAN) is effective for the treatment of depression. A supplement to NDA 11–961 providing for this indication was approved in 1998. Isocarboxazid is no longer entitled to the temporary exemption announced in 1978. Accordingly, the exemption, as it pertains to isocarboxazid, is hereby revoked.

No other monoamine oxidase inhibitor remains exempt under the paragraph XIV, category XX exemption, and category XX is now dissolved.

Isocarboxazid is regarded as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), and an approved application, under section 505 of the act (21 U.S.C. 355), is required for marketing an isocarboxazid product.

In addition to the product specifically named in the previous paragraphs, this document applies to any product that is not the subject of an approved application and is identical to the product named previously. The document may also be applicable, under § 310.6 (21 CFR 310.6), to a similar or

related drug product that is not the subject of an approved application. It is the responsibility of every drug manufacturer or distributor to review this document and to determine whether it covers any drug product that the person manufactures or distributes. Any person may request an opinion of the applicability of this document to a specific drug product by writing to the Division of New Drugs and Labeling Compliance (see **ADDRESSES**).

II. Conditions for Approval and Marketing

A. Effectiveness Classification

FDA has reviewed all available evidence and concludes that isocarboxazid is effective for the indication in the labeling conditions listed in the following sections. The drug product lacks substantial evidence of effectiveness for other labeled indications.

B. Conditions for Approval and Marketing

FDA is prepared to approve ANDAs referencing MARPLAN for products containing isocarboxazid for the indication now regarded as effective.

1. Form of Drug

The drug product is in tablet form for oral administration. Each tablet contains isocarboxazid, 10 mg.

2. Labeling Conditions

a. *The label bears the statement ''Rx only''.*

b. The drug is labeled to comply with all requirements of the act and FDA's regulations, and the labeling bears adequate information for safe and effective use of the drug. The indication is as follows:

Isocarboxazid is indicated for the treatment of depression. Because of its potentially serious side effects, isocarboxazid is not an antidepressant of first choice in the treatment of newly diagnosed depressed patients.

The efficacy of isocarboxazid in the treatment of depression was established in 6-week controlled trials of depressed outpatients. These patients had symptoms that corresponded to the Diagnostic and Statistical Marwal of Mental Disorders (DSM–IV) category of major depressive disorder; however, they often also had signs and symptoms of anxiety (anxious mood, panic, and/or phobic symptoms). (See Clinical Pharmacology.)

A major depressive episode (DSM–IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and a suicide attempt or suicidal ideation.

The antidepressant effectiveness of isocarboxazid in hospitalized depressed patients, or in endogenomorphically retarded and delusionally depressed patients, has not been adequately studied.

The effectiveness of isocarboxazid in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use isocarboxazid for extended periods should periodically evaluate the long-term usefulness of the drug for the individual patient.

3. Marketing Status

For unapproved products, approval of an ANDA must be obtained in accordance with section 505(j) of the act before marketing such products. Marketing prior to approval of an ANDA will subject such products, and those persons who caused the products to be marketed, to regulatory action.

III. Notice of Opportunity for Hearing

Notice is given to the holder of the NDA and to all other interested persons that the Director of CDER proposes to issue an order under section 505(e) of the act withdrawing approval of the NDA and all amendments and supplements thereto providing for indications that lack substantial evidence of effectiveness (i.e., indications not referred to in section II.B.2.b of this document). The basis of the proposed action is that new information before the Director of CDER with respect to the drug product, evaluated together with the evidence available to the Director of CDER when the application was approved, shows there is a lack of substantial evidence that the drug product will have all the effects it claims or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling for indications not referred to in section II.B.2.b of this document. If no hearing is requested, then approval of the claims that lack evidence of effectiveness will be considered withdrawn, and no further order will issue.

This notice of opportunity for hearing encompasses all issues relating to the legal status of the drug product subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962 (Public Law 87–781), or for any other reason.

In accordance with section 505 of the act and the regulations issued under that section (21 CFR part 310 and part 314 (21 CFR part 314)), an applicant and all other persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named in this document (§ 310.6) and not the subject of an NDA are hereby given an opportunity for a hearing to show why approval of those portions of the NDA providing for indications that lack substantial evidence of effectiveness should not be withdrawn, and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug product named above and of all identical, related, or similar drug products not the subject of an NDA.

The applicant or any other person subject to this document under § 310.6 who decides to seek a hearing shall file: (1) A written notice of appearance and request for hearing (see **DATES**), and (2) the data, information, and analyses relied on to justify a hearing, as specified in § 314.200 (see **DATES**). Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing; a notice of appearance and request for hearing; a submission of data, information, and analyses to justify a hearing; other comments; and a granting or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of the applicant or any other person subject to this notice under § 310.6 to file a timely written notice of appearance and request for hearing, as required by § 314.200, constitutes an election by the person not to make use of the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product. Any such drug product labeled for the indications referred to in this notice as lacking substantial evidence of effectiveness may not thereafter lawfully be marketed, and the FDA will initiate appropriate regulatory action to remove such drug product from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual

analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under the authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.100).

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8658 Filed 4–15–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Pilot Testing of Outcome Measures in Programs Providing Services to Persons Who are Homeless and Have Serious Mental Illnesses—New—SAMHSA's Center for Mental Health Services (CMHS) provides funds to states and territories to provide services to individuals who are homeless and have serious mental illnesses. These services enable persons who are homeless and have serious mental illnesses to be placed in appropriate housing situations and linked to mental health services. To comply with requests for client outcome data, State and local providers have sought measures which could help them more effectively monitor and manage their programs as well as demonstrate program effectiveness.

Interest in performance measurement and evaluation of policies, programs and individual services has increased dramatically with the passage of the Government Performance and Results Act (GPRA) in 1993. GPRA focuses new attention on the quality of outcome measures used to collect information about publicly funded programs. Programs that provide services to persons who are homeless and have serious mental illnesses are facing greater need to document their effectiveness. These outcome data will ultimately be used in responding to Congressional and HHS oversight, GPRA requirements, and the requests of other governmental levels, managed care companies, and private funding sources.

The project will test the appropriateness and feasibility of selected indicators to measure the outcome of services to persons who are homeless and have serious mental illnesses. Outcome measures to be evaluated include housing status, sobriety or drug-free status, mental health treatment status, enrollment in an educational program, and employment.

In addition, the project will evaluate process measures pertaining to outreach, service delivery and linkage stages of intervention. These process indicators include the type of contact (*i.e.*, referrals, walk-ins, fixed outreach, and mobile outreach); whether the person contacted agreed to services, reasons for any non-enrollment, and referral to, and provision of, specific services.

The project will test these outcome and process measures in a total of approximately six provider agencies in each of five participating States. The findings of the pilot test will serve as the basis for recommendations for a national implementation of data collection in similar programs. It will also test the feasibility of compiling such data in a central data collection point.

Local providers will report information on services provided to individuals served during an initial 30-day period. Providers will use the Individual Data Collection Form to record information about client characteristics for the time of first contact and during the 30-day period; the Individual Intervention and Linkage Form will be completed to capture information specific to referrals and receipt of services; and the 3-Month Follow-up Form will be completed three months after the end of the initial data collection period to provide more longitudinal information on participant status. No client-identified information will be submitted. After each period of data collection, local providers will be contacted by telephone to obtain feedback on the structure and utility of the data collection instruments, the process of collecting and reporting the data, and the overall burden associated with the data collection and submission effort. Projected response burden for the project is summarized in the table below.

	Estimated number of respondents	Responses per respondent	Average burden hours per response	Total annual burden hours
Individual Data Collection Form	30	20	.17	102
Individual Intervention and Linkage Form	30	20	.17	102
3-Month Follow-up Form	30	20	.06	36
Provider Survey	30	2	.50	30
Total				270

Written comments and recommendations concerning the proposed information collection should be sent by May 17, 2004 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.