

Request for Information From U.S. Processors That Export to the European Community—(OMB Control Number 0910-0320)—Extension

The European Community (EC) is a group of 15 European countries (with 10 additional countries joining on May 1, 2004), that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intraEC trade has been extended to trade with nonEC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors

that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

1. Business name and address;
2. Name and telephone number of person designated as business contact;

3. Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;

4. Name and address of manufacturing plants for each product;

5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection; and

6. Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of 18 U.S.C 1001. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Products	No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	0.25	3
Dairy	100	1	100	0.25	25
Game Meat and Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					32

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN; DISCLOSURE¹

Respondent	No. of Respondents	No. of Responses per Respondent	Total annual Responses	Hours per Response	Total Hours
Trade Association	15	1	15	8	120
State	50	1	50	8	400
Total					520

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

It is estimated that the annual reporting burden would be no more than 32 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. The number of respondents is a rough estimate based on volume of exports and responses received to date. No record retention is required. Therefore, the proposed annual burden for this information collection is 32 hours.

Dated: April 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0267]

Agency Information Collection Activities; Announcement of OMB Approval; Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Postmarketing Studies for Human Drugs and Licensed Biological Products;

Status Report" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 16, 2004 (69 FR 2601), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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.

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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