

Attachment D—Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and believe that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) have not within a 3-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transaction." provided below without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions (To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

(b) where the prospective lower tier participant is unable to certify to any of the

above, such prospective participant shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled "certification Regarding Debarment, Suspension, Ineligibility, Voluntary Exclusion—Lower Tier Covered Transactions." without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Attachment E—Certification Regarding Environmental Tobacco Smoke

Public Law 103-227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for children's services and that all subgrantees shall certify accordingly.

[FR Doc. 95-10029 Filed 4-21-95; 8:45 am]

BILLING CODE 4184-01-P

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Food Advisory Committee (the Committee) in FDA's Center for Food Safety and Applied Nutrition. Nominations will be accepted for current vacancies and vacancies that will or may occur on the Committee during the next 12 months.

FDA has special interest in ensuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for

appropriately qualified female, minority, or physically handicapped candidates. Final selection from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Nominations should be received by May 24, 1995.

ADDRESSES: All nominations for membership, except for consumer-nominated members, should be sent to Catherine M. DeRoever (address below). All nominations for the consumer-nominated members should be sent to Martha F. Waugh or Annette J. Funn (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except for consumer-nominated members: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS-22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4251.

Regarding all nominations for consumer-nominated members: Martha F. Waugh or Annette J. Funn, Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the advisory committee listed below. Individuals should have expertise in the activity of the Committee. Eight vacancies will occur June 30, 1995.

Food Advisory Committee

The Committee provides advice primarily to the Director, Center for food Safety and Applied Nutrition, and as needed, to the Commissioner of Food and Drugs, and other appropriate officials, on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade. The Committee also provides advice and makes recommendations on ways of communicating to the public the potential risks associated with these issues and recommends approaches to be considered in addressing them.

Criteria for Members

Persons nominated for membership on the Committee shall be knowledgeable in the fields of life sciences, food science, risk assessment, or other relevant scientific disciplines. The Committee may include technically qualified members who are identified

with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons.

Representatives of industry interests will serve as liaisons to the regulated industry. The term of office is up to 4 years.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude Committee membership. Additionally, the nominee's mailing address, telephone number, and curriculum vitae must accompany the nominations. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, employment, consultancies, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Criteria for Consumer-Nominated Members

Selection of representatives of consumer interests will be conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Candidates from this group, like all other candidates for membership on the Committee, should possess appropriate qualifications to understand and contribute to the Committee's work.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others and to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Committee. The

agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Committee's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Committee's work if the individual(s) had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95-10075 Filed 4-21-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95E-0035]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUVOX™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUVOX™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory

review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LUVOX™ (fluvoxamine maleate). LUVOX™ is indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LUVOX™ (U.S. Patent No. 4,085,225) from Duphar International, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 1, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LUVOX™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LUVOX™ is 6,958 days. Of this time, 5,886 days occurred during the testing phase of the regulatory review period, while 1,072 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* November 19, 1975. FDA has verified the applicant's claim that the date the investigational new drug application