Certification Regarding Drug-Free Workplace Requirements (Instructions for Certification)

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. For grantees other than individuals, Alternate I applies.

4. For grantees who are individuals, Alternate II applies.

5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All direct charge employees; (ii) All indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about—

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within 10 calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted —

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

(B) The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0033]

Guidance for Industry on Internal Radioactive Contamination—Development of Decorporation Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' This document provides guidance to industry on the development of decorporation agents for the treatment of internal radioactive contamination when evidence is needed to demonstrate the effectiveness of the agents, but human efficacy studies are unethical or infeasible. In such instances, the animal efficacy rule may be invoked to approve new decorporation agents not previously

marketed or new indications for previously marketed drug products. Specifically, this guidance addresses chemistry, manufacturing, and controls (CMC) information; animal efficacy, safety pharmacology, and toxicology studies; clinical pharmacology, biopharmaceutics, and human safety studies; and postapproval commitments.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stewart, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' This guidance is being issued to facilitate the development of new decorporation agents or new uses of previously marketed drug products for the treatment of internal radioactive contamination.

In the **Federal Register** of February 15, 2005 (70 FR 7747), FDA announced the availability of a draft version of the guidance document entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' No comments were received and, with one exception, only minor editorial changes have been made. The references to biological products have been removed from the guidance because FDA does not expect many products developed for use as decorporation agents to be biologics.

Internal radioactive contamination can arise from accidents involving nuclear reactors, industrial sources, or medical sources. The potential for these accidents has been present for many years. Recent events also have highlighted the potential for nonaccidental radioactive contamination as a result of criminal or terrorist actions. Internal contamination occurs when radioactive material is ingested, inhaled, or absorbed from a contaminated wound. As long as these radioactive contaminants remain in the body, they may pose significant health risks. Long-term health concerns include the potential for the development of cancers of the lung, liver, thyroid, stomach, and bone and, when a radioactive contaminant is inhaled, for the development of fibrotic changes in the lung that may lead to restrictive lung disease. The only effective method of reducing these risks is removal of the radioactive contaminants from the body.

''Decorporation agents'' refer to medical products that increase the rate of elimination or excretion of inhaled, ingested, or absorbed radioactive contaminants. The effectiveness of most decorporation agents for the treatment of internal radioactive contamination cannot be tested in humans because the occurrence of accidental or nonaccidental radioactive contamination is rare, and it would be unethical to deliberately contaminate human volunteers with potentially harmful amounts of radioactive materials for investigational purposes.

FDA is issuing this guidance to industry to facilitate the development of new decorporation agents or new indications for previously marketed drug products that may be eligible for approval under the animal efficacy rule (21 CFR 314.600–314.650). As set forth in this rule, under certain circumstances animal studies can be relied on to provide substantial evidence of effectiveness of a product. Evaluation of the product for safety in humans is still required, and cannot be addressed by animal studies alone. The adequacy of human safety data will need to be assessed based on clinical pharmacology and safety studies conducted in humans. This guidance addresses the design and conduct of the requisite CMC, animal efficacy, safety pharmacology, toxicology, clinical pharmacology, biopharmaceutics, and human safety studies needed to support approval of new decorporation agents or new uses of previously marketed drug products for the treatment of internal radioactive contamination.

In addition, approval under the animal efficacy rule is subject to certain postapproval commitments, including submission of a plan for conducting postmarketing studies that would be feasible should an accidental or intentional release of radiation occur; postmarketing restrictions to ensure safe use, if deemed necessary; and product labeling information intended for the patient advising that, among other things, the product's approval was based on effectiveness studies conducted in animals alone. This guidance addresses the postapproval commitments that would be needed for approval of a new decorporation agent or for a new indication for a previously approved drug product under the animal efficacy rule.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the development of decorporation agents for the treatment of internal radioactive contamination. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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