merchandise to the owner of the protected work for examination, testing, or any other use in pursuit of a related private civil remedy for copyright infringement. To obtain a sample under this section, the owner of the protected work must furnish to CBP a bond in the form and amount specified by the port director at the port of importation, conditioned to hold the U.S., its officers and employees, and the importer or owner of the imported article harmless from any loss or damage resulting from the furnishing of a sample by CBP to the copyright owner. This requirement may be waived at the discretion of the port director where the value of the sample is less than $50.00. CBP may demand the return of the sample at any time. The owner of the protected work must return the sample to CBP upon demand or at the conclusion of the examination, testing, or other use in pursuit of a related private civil remedy for copyright infringement. In the event that the sample is damaged, destroyed, or lost while in the possession of the owner of the protected work, the owner of the protected work must, in lieu of return of the sample, certify to CBP that: ''The sample described as [insert description] provided by CBP pursuant to § 133.42(e) of the CBP Regulations was (damaged/destroyed/lost) during examination, testing, or other use.''

(f) *Parallel Imports.* Copies or phonorecords made lawfully and imported into the U.S. without the consent of the owner of the protected copyrighted work, are not subject to detention, seizure, or forfeiture by CBP.

§ 133.43 [Removed]

8. Section 133.43 is removed and reserved.

§ 133.44 [Removed]

9. Section 133.44 is removed and reserved.

10. Section 133.46 is revised to read as follows:

§ 133.46 Demand for redelivery of released articles.

If CBP determines that articles which have been released from CBP custody are subject to the prohibitions or restrictions of this subpart, the appropriate field officer will promptly make demand for redelivery of the articles pursuant to § 141.113 of this chapter, under the terms of the bond on CBP Form 301, containing the bond conditions set forth in § 113.62 of this chapter. If the articles are not redelivered to CBP custody, a claim for liquidated damages may be made in accordance with § 141.113(h) of this chapter.

Dated: September 30, 2004.

Robert C. Bonner,

Commissioner of Customs and Border Protection.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 04–22334 Filed 10–4–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 361

[Docket No. 2004N–0432]

Radioactive Drugs for Certain Research Uses; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the use of certain radioactive drugs for research purposes without an investigational new drug application (IND) under the conditions set forth in FDA regulations (typically, use of radioactive drugs to determine drug disposition in the body). We are seeking public input on the potential need to modify the conditions under which these radioactive drugs are studied in light of the scientific and technological developments since we adopted the regulations in 1975.

DATES: The public meeting will be held on November 16, 2004, from 8 a.m. to 4 p.m. Submit electronic requests to speak plus a presentation abstract by October 19, 2004, to Maria R. Walsh. Submit final presentations and requests for special accommodations (due to disability) by November 2, 2004, to Maria R. Walsh. Submit written or electronic comments by January 16, 2005, to Division of Dockets Management.

ADDRESSES: The public meeting will be held at the CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857.

You may submit comments, identified by Docket No. 2004N–0432, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0432 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts, or go to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts of the public meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets*.

FOR FURTHER INFORMATION CONTACT: Maria R. Walsh, Center for Drug Evaluation and Research (HFD–103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3139, FAX 301–480–3761, e-mail: *walsh@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing a public meeting to discuss research on radioactive drugs that is conducted under § 361.1 (21 CFR 361.1). We added this section to FDA regulations in 1975 (40 FR 31298 at 31308, July 25, 1975). Under § 361.1, certain radioactive drugs (drugs that exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons) are considered generally recognized as safe and effective under specified conditions of use when administered to human research subjects for certain basic research uses. These uses include studies intended to obtain basic information regarding the metabolism (including pharmacokinetics,

distribution, and localization) of a radioactive drug or regarding human physiology, pathophysiology, or biochemistry, but not those intended for immediate therapeutic, diagnostic, or similar purposes or those intended to determine the safety and effectiveness of the drug. When conducted in accordance with § 361.1, clinical investigations of radioactive drugs are not subject to the requirements for INDs stated in part 312 (21 CFR part 312).

In general, to conduct studies using radioactive drugs under § 361.1, an FDA-approved Radioactive Drug Research Committee (RDRC) must first conclude the following:

1. The pharmacological dose is limited such that the amount of active ingredient or ingredients administered is known not to cause any clinically detectable pharmacological effect, based on data available from published literature or from other valid human studies (§ 361.1(b)(2) and (d)(2)).

2. The radiation dose is limited such that the amount of radioactive material administered is the smallest radiation dose practical to perform the study without jeopardizing the benefits obtained from the study, and the dose, for adult subjects, does not exceed the following:

TABLE 1.—LIMITS OF RADIATION DOSE FOR ADULTS

Organ or System	Single Dose Sieverts (Rems)	Annual and Total Dose Sieverts (Rems)
Whole body	0.03 (3)	0.05 (5)
Active blood-forming organs	0.03 (3)	0.05 (5)
Lens of the eye	0.03 (3)	0.05 (5)
Gonads	0.03 (3)	0.05 (5)
Other organs	0.05 (5)	0.15 (15)

For subjects under 18 years of age, the radiation dose must not exceed 10 percent of the adult dose (§ 361.1(b)(3)).

3. The design and quality of the study and the importance of the information it seeks to obtain justify the exposure of research subjects to radiation (§ 361.1(b)(1)(iii)).

4. The investigator has appropriate qualifications for the conduct of a study involving radioactive drugs (§ 361.1(d)(3)).

5. The investigator has the appropriate licensure for handling radioactive materials (§ 361.1(d)(4)).

6. The mechanisms for selecting research subjects and obtaining informed consent are appropriate (§ 361.1(d)(5)).

7. The radioactive drug to be administered meets appropriate chemical, pharmaceutical, radiochemical, and radionuclidic standards for identity, strength, quality, and purity; and radioactive drugs for parenteral use are prepared in sterile and pyrogen-free form (§ 361.1(d)(6)).

8. The study is based on a sound rationale and is of sound design such that information of scientific value may result (§ 361.1(d)(7)).

9. There are mechanisms in place for identifying and reporting adverse reactions (§ 361.1(d)(8)).

10. The study has been reviewed and approved by an institutional review board (IRB) (§ 361.1(d)(9)).

Since we added § 361.1 in 1975, there have been numerous developments in imaging technology, pharmacology, toxicology, and dosimetry that have had a significant impact on the use of radioactive drugs. In light of these changes, we are considering whether issuance of guidance on, or even revision of, § 361.1 would be appropriate. To that end, we are holding a public meeting to obtain input on what actions we should take, if any, concerning the regulation of basic research involving radioactive drugs. To facilitate discussion at the public meeting and assist us in our review of this matter, we have the following questions concerning the application of § 361.1:

1. *Pharmacology Issues*: Section 361.1(b)(2) requires that the amount of radioactive drug to be administered be known not to cause any clinically detectable pharmacological effect in humans. According to § 361.1(d)(2), investigators must provide pharmacological dose calculations based on published literature or other human data to demonstrate an absence of a clinically detectable pharmacological effect (thus, no radioactive drug may be studied ''first in humans'' under current § 361.1).

a. For an active ingredient chemically manufactured in the laboratory that is also a body constituent (an endogenous substance), what percentage of estimated daily endogenous production could be considered to have no pharmacological effect? (Because heterogeneous biological products (e.g., monoclonal antibodies and therapeutic proteins such as interferon, interleukin, other cytokines, and enzymes) are foreign proteins and are assumed to have the potential to produce an antigenic response, they should be excluded from consideration unless they have been shown to have no immunologic response.)

b. For an active ingredient that is not endogenous, what animal, in vitro, and/or in vivo data would be needed to demonstrate that there is no human pharmacological effect? Is there an absolute dose that would ensure no pharmacological effect? If so, what data would be needed to support that dose?

c. How may an investigator confirm that a radioactive drug causes no clinically detectable pharmacological effect in humans in accordance with § 361.1(b)(2)? What parameters should be measured, how frequently, and what criteria should be used to determine if a pharmacologic effect has occurred?

2. *Radiation Dose Limits for Adult Subjects*: The radiation dose limits for adult subjects specified in § 361.1(b)(3)(i) are based on the basic occupational radiation protection criteria established by the Nuclear Regulatory Commission under 10 CFR 20.101. FDA's thinking in 1975 was that these criteria would enable a potential research subject to make an informed decision regarding participation in a study under § 361.1 because the subject would, in effect, be deciding whether he or she was willing to assume the same risk as a radiation worker for the duration of the study. Considering the advances in scientific knowledge and regulatory changes that have occurred

since 1975, including new data on radiation effects (Ref. 1) and new recommendations on radiation dose limits (Refs. 2, 3, and 4), are the current dose limits for adults still appropriate for research conducted under § 361.1? If not, what dose limits are appropriate? Should there be different dose limits for different adult age groups?

3. *Assurance of Safety for Pediatric Subjects*: Currently, § 361.1 allows for the study of radioactive drugs in subjects less than 18 years of age without an IND if:

- The study presents a unique opportunity to gain information not currently available, requires the use of research subjects less than 18 years of age, is without significant risk to subjects, and is supported with review by qualified pediatric consultants to the RDRC;
- The radiation dose does not exceed 10 percent of the adult radiation dose specified in § 361.1(b)(3)(i); and
- As with adult subjects, the following requirements, among others, are met: (1) The study is approved by an institutional review board (IRB) that conforms to 21 CFR part 56, (2) informed consent of the subjects' legal representative is obtained in accordance with 21 CFR part 50, and (3) the study is approved by the RDRC that assures all other requirements of § 361.1 are met.

Alternatively, when a study is conducted under an IND in accordance with part 312, the sponsor must submit to FDA the study protocol, protocol changes and information amendments, pharmacology/toxicology and chemistry information, and information regarding prior human experience with the same or similar drugs (see §§ 312.22, 312.23, 312.30, and 312.31). Additionally, § 312.32 requires that sponsors promptly review all information relevant to the safety of the drug obtained or otherwise received by the sponsor from any source, foreign or domestic. This includes information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities. Section 312.32 also requires that sponsors submit IND safety reports to FDA.

a. Does § 361.1 provide adequate safeguards for pediatric subjects during the course of a research project intended to obtain basic information about a radioactive drug, or should these studies only be conducted under an IND?

b. If we assume that § 361.1 provides adequate safeguards for pediatric subjects during such studies, given our present knowledge about radiation and its effects, can we conclude that the current dose limits for pediatric subjects do not pose a significant risk? If not, what dose limits would be appropriate to ensure no significant risk for pediatric subjects? Should there be different dose limits for different pediatric age groups?

4. *Quality and Purity*: What standards for quality and purity should apply to radioactive drugs administered under § 361.1 to ensure the safety of research subjects?

5. *Exclusion of Pregnant Women*: Section 361.1(d)(5) requires that each female research subject of childbearing potential state in writing that she is not pregnant or, on the basis of a pregnancy test, be confirmed as not pregnant before she may participate in any research study involving a radioactive drug under § 361.1. Is written attestation adequate assurance that female research subjects are not pregnant? If not, what other assurance should be provided?

6. *RDRC Membership*:

a. Under § 361.1(c)(1), an RDRC must include the following expertise: (1) A physician recognized as a specialist in nuclear medicine, (2) a person qualified to formulate radioactive drugs, and (3) a person with special competence in radiation safety and radiation dosimetry. Would an RDRC benefit from any additional expertise, such as a pharmacologist or toxicologist? Should such memberships be required?

b. Under § 361.1(c)(4), changes in the membership of an RDRC must be submitted to FDA as soon as, or before, vacancies occur on the committee. However, the regulations do not require approval of new members by FDA before a new member assumes committee responsibilities. We review the qualifications of new members when we receive them and contact the RDRC when we identify new members we consider to be unqualified, but we do not always receive notifications of changes in membership in a timely manner. At times, this has resulted in unqualified members serving on RDRCs for extended periods. Should the regulations specifically require that FDA approve RDRC membership changes before new members assume committee responsibilities? For example, would it be appropriate for the regulations to allow FDA 15 days to review the qualifications of a proposed new member before the member could assume committee responsibilities?

II. Registration and Presentations

No registration is required to attend the meeting. Seating is limited to 120 and will be on a first-come, first-served basis. If you need special accommodations due to a disability, please inform Maria R. Walsh by November 2, 2004.

If you wish to present information at the public meeting, submit your electronic request and an abstract of your presentation by the close of business on October 19, 2004, to Maria Walsh (see **FOR FURTHER INFORMATION CONTACT**).

The request to participate should contain the following information:

(1) Presenter's name; (2) address; (3) telephone number; (4) e-mail address; (5) affiliation, if any; (6) abstract of the presentation; and (7) approximate amount of time requested for the presentation.

We request that persons and groups having similar interests consolidate their comments and present them through a single representative. We will allocate the time available for the meeting among the persons who request to present. Because of limited time, we will accept only one presenter per organization. We reserve the right to deny requests if the proposed topic is not germane. After reviewing the requests to present and abstracts, we will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Presenters planning to use electronic presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Acrobat PDF must send them to us by the close of business on November 2, 2004. Presenters who do not meet this deadline may provide handouts of their presentations at the meeting.

The meeting schedule will be available on the Internet at *http://www.fda.gov/cder/meeting/clinicalResearch/default.htm* and at the meeting. After the meeting, the schedule and presentations will be placed on file in the Division of Dockets Management under the docket number listed in the heading of this notice.

III. Comments

Interested persons may submit written or electronic comments on or before January 16, 2005, to the Division of Dockets Management (see **ADDRESSES**). You must submit two copies of comments identified with the docket number found in brackets in the heading of this document. The received comments may be seen at the Division of Dockets Management, Monday through Friday between 9 a.m. and 4 p.m.

IV. Transcripts

Approximately 30 days after the public meeting, you can examine a transcript of the meeting on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm* or at the Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, at a cost of 10 cents per page or on CD at a cost of $14.25 each.

V. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Preston, D.L., Y. Shimizu, D.A. Pierce, A. Suyama, and K. Mabuchi, ''Studies of mortality of atomic bomb survivors, Report 13: Solid cancer and noncancer disease mortality: 1950–1997,'' Vol. 160, No. 4, pp. 381–407, Radiation Research, 2003.

2. International Commission on Radiological Protection, ''1990 Recommendations of the International Commission on Radiological Protection,'' Annals of the International Commission on Radiological Protection (ICRP), ICRP Publication 60, vol. 21, No. 1–3, pp. 1–201, 1991.

3. National Council on Radiation Protection Measurements (NCRP), ''Limitation of Exposure to Ionizing Radiation,'' NCRP Report no. 116, Bethesda, MD, 1993.

4. National Council on Radiation Protection and Measurements, ''Principles and Application of Collective Dose in Radiation Protection,'' NCRP Report No. 121, Bethesda, MD, 1995.

Dated: September 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22354 Filed 10–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 48

[REG–120616–03]

RIN 1545–BC08

Entry of Taxable Fuel; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document contains a notice of public hearing on proposed regulations relating to the tax on the entry of taxable fuel into the United States.

DATES: The public hearing is being held on January 12, 2005, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by December 1, 2004.

ADDRESSES: The public hearing is being held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

Mail outlines to: CC:PA:LPD:PR (REG–120616–03) , room 5203, Internal Revenue Service POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–120616–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS-REG–120616–03).

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing LaNita Van Dyke, (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed regulations (REG–120616–03) that was published in the **Federal Register** on Friday, July 30, 2004 (69 FR 45631).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who have submitted written comments and wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight copies) by December 1, 2004.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of agenda will be made available, free of charge, at the hearing. Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Associate Chief Counsel, Legal Processing Division (Procedures and Administration).

[FR Doc. 04–22372 Filed 10–4–04; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI117–01–7347b; FRL–7637–1]

Approval and Promulgation of Implementation Plans; Wisconsin

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Wisconsin regulations as they pertain to Northern Engraving Corporation (NEC) facilities in Galesville and West Salem, Wisconsin as requested by the State of Wisconsin on June 27, 2003. This State Implementation Plan (SIP) revision makes changes to Wisconsin air pollution control rules federally enforceable. The rule revisions modify the emission limits adopted by the state that are part of the current Wisconsin SIP. The revised rules, specifically portions of the Environmental Cooperative Agreement with NEC, supercede portions of the rules in the Wisconsin SIP.

In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's request as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. The rationale for approval is set forth in the direct final rule. If EPA receives no written adverse comments, EPA will take no further action on this proposed rule. If EPA receives written adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect. In that event, EPA will address all relevant public comments in a subsequent final rule based on this proposed rule. In either event, EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Comments on this action must be received by November 4, 2004.