Dated: June 15, 2001.

Laura Yoshii,

Acting Regional Administrator, Region IX.

[FR Doc. 01–16947 Filed 7–5–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 450

[FRL–7008–7]

RIN 2040–AD42

Effluent Limitations Guidelines and New Source Performance Standards for the Construction and Development Point Source Category; Announcement of Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice, announcement of meetings.

SUMMARY: EPA will conduct informational meetings on the upcoming Construction and Development (C&D) Effluent Guidelines proposed rulemaking. The Agency will provide an overview of the C&D project. EPA intends to propose effluent guidelines and standards for the C&D category in March 2002. The meetings are open to the public, and limited seating is available on a first-come, first-served basis.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for meeting locations.

FOR FURTHER INFORMATION CONTACT: Eric Strassler, Engineering and Analysis Division (4303), EPA Office of Water, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (202) 260–7150; e-mail: *strassler.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is developing proposed effluent limitations guidelines and standards for the C&D Point Source Category under authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*). The C&D effluent guidelines will establish technology-based standards for discharges from construction sites regulated by the National Pollutant Discharge Elimination System (NPDES). The C&D rule will cover construction activities associated with new development and re-development. The regulations will address stormwater runoff from construction sites during the active phase of construction, as well as post-construction runoff. The industrial sectors which are being examined during the rulemaking include residential buildings, non-residential buildings, heavy construction, and land development. Additional information is available on the C&D website at *http://www.epa.gov/ost/guide/construction/.*

The meetings will provide an update on the development of the proposed rule. EPA will discuss the data collection efforts, the potential technology options, and the schedule for the C&D rulemaking. The meetings are not a mechanism for submitting formal comments. The meetings will not be recorded by a reporter nor transcribed for inclusion in the administrative record for the C&D rulemaking. Limited seating is available on a first-come, first-served basis.

A more detailed agenda and other documents related to the C&D project will be available at the meetings. For those unable to attend a meeting, EPA will make documents available at the EPA website listed above, and they can be obtained by an e-mail or telephone request to Eric Strassler at the above address.

Meeting Times and Locations

1. Tuesday, July 24, 2001, 9:00 am to 12:00 noon. EPA Education Center Auditorium, Waterside Mall, 401 M Street, SW., Washington, DC. Directions: The Auditorium is located on the ground floor at the rear of the Waterside Mall complex. Limited parking is available in the vicinity of the mall. EPA recommends that attendees travel by Metro subway to the Waterfront station (Green line). Upon exiting the Metro station, enter Waterside Mall, proceed to the rear exit (I Street), and turn left to reach the EPA Education Center.

2. Wednesday, August 1, 2001, 9:00 am to 12:00 noon. Executive Tower Hotel, 1405 Curtis Street, Denver, CO. For information on accommodations and directions to the hotel, please telephone 800–525–6651 or see the hotel website at *http://www.exectowerhotel.com.*

Dated: June 28, 2001.

Louise P. Wise,

Acting Director, Office of Science and Technology.

[FR Doc. 01–16953 Filed 7–5–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0940–AA03

Protection of Human Research Subjects

AGENCY: Department of Health and Human Services (DHHS).

ACTION: Notice of Proposed Rule Making.

SUMMARY: The Department of Health and Human Services (DHHS) is proposing to amend Subpart B of its human subjects protection regulations published on January 17, 2001. These regulations provide additional protections for pregnant women and human fetuses involved in research and pertain to human in vitro fertilization. The rule continues the special protections for pregnant women and human fetuses that have existed since 1975. The Department proposes to amend the regulations by making limited changes in terminology referring to neonates, clarifying provisions for paternal consent when research is conducted on fetuses, and clarifying language that applies to research on newborns of uncertain viability.

DATES: Comments on the proposed regulation must be received on or before September 4, 2001.

ADDRESSES: Comments must be sent to: Irene Stith-Coleman, Ph.D., Office of Human Research Protections (OHRP) 200 Independence Avenue, SW., Room 733–E, Washington, DC, 20201. Telephone 202–260–1587. Email *istithco@osophs.dhhs.gov.* The Department invites written comments on the proposed regulations and requests that comments identify the specific regulatory provisions to which they relate.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office of Human Research Protections (OHRP) 200 Independence Avenue, SW., Room 733–E, Washington, DC, 20201. Telephone 202–260–1587. Interested persons may obtain a copy of the current regulations for the protection of human subjects, including Subpart B, at *http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.*

SUPPLEMENTARY INFORMATION:

Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by the agency through regulations codified at Title 45, part 46,

of the Code of Federal Regulations. Subpart B of 45 CFR part 46, promulgated on August 8, 1975, pertains to research involving fetuses, pregnant women, and human in vitro fertilization. The 1975 regulations were jointly published in the **Federal Register** with the report and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research on the Fetus (40 FR 33526). Subsequent changes were incorporated January 11, 1978 (43 FR 1758), November 3, 1978 (43 FR 51559), and June 1, 1994 (59 FR 28276).

On January 17, 2001, the Department published in the **Federal Register** a Final Rule, with an effective date of March 19, 2001 (66 FR 3878), intended to amend Subpart B of 45 CFR Part 46. This preamble refers to that rule as ''the January rule.'' The January rule's effective date was delayed by 60 days on March 19, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled A Regulatory Review Plan, published in the **Federal Register** on January 24, 2001. (66 FR 15352). The effective date of the January rule was further delayed by 180 days on May 18, 2001 to give the Department an opportunity to obtain comment on three modifications to the rule. (66 FR 27559).

The Department determined that there was a need to delay the January rule's effective date to seek public comment on three limited aspects: (1) Whether paternal consent (when the father is readily available) should be obtained for participation in federally funded research that is directed solely at a fetus; (2) whether the definition of ''fetus'' should be modified so that it describes only the stage prior to delivery; and (3) whether the rule should be modified to make clear that fetuses of uncertain viability may be subjected to added risk only if the research is intended to enhance the probability of survival of the particular fetus to the point of viability.

First, the Department proposes to require a father's consent (when the father is readily available) for participating in research that is directed solely at a fetus and that does not affect a mother's health. We believe that this approach is the most respectful of the parents' joint interests in their fetus's health. In this narrow situation, the January rule allowed the mother alone to consent for the research on the fetus. The preamble to the January rule explained that consent requirements for research involving pregnant women were modified to address cases in which a requirement for the father's consent had been a barrier to participation in research which held potential benefit for both pregnant women and their fetuses. We believe that this problem is addressed by the clarification in this rule that only the mother's consent is required for participation in research that may benefit both the pregnant woman and the fetus. In keeping with the January rule, a father's consent would not be needed for a woman to participate in a research activity that would benefit her health.

Second, the Department proposes to add to the regulations the term ''neonate'' to describe an infant that has been delivered but for which a viability determination has not yet been made. The January rule uses the term ''fetus'' to describe not only infants at the stage prior to delivery, but also just-delivered newborns. We believe that using the term ''fetus'' only for those infants that have not been delivered is preferable because it is more consistent with the ordinary understanding of that word and because using the term neonate for a fetus that has been delivered is more appropriate. We propose to use the term ''neonate'' to describe a newborn for which a viability determination has not yet been made. This modification will not change the strong protections the rule gives to pregnant women and fetuses, or change the regulatory framework that has been established to guide decisions regarding conduct of federally-supported research.

Third, the Department proposes to clarify the language that governs decisions regarding conduct of federally-supported research on neonates of uncertain viability. Some changes in wording were introduced in the January rule that may have created confusion on this issue. We wish to make clear that these neonates may be subjected to added risk only if the research is intended to enhance the particular neonate's probability of survival to the point of viability.

The Department proposes other minor clarifying and technical changes that are consistent with these proposed amendments.

Proposed Changes to Subpart B

Title Subpart B—Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization

The title is changed to add the word ''neonate.''

Section 46.201 To what do these regulations apply?

Paragraph (a)—There is no substantive change to this paragraph. The word ''neonate'' is added to reflect that the rule covers neonates.

Paragraphs (b)–(d)—No change.

Section 46.202—Definitions

Paragraph (a)—The definition of ''dead fetus'' is modified by changing the word ''fetus'' to ''neonate.'' The words ''after delivery'' are deleted to avoid redundancy.

Paragraph (b)—The definition of ''fetus'' is modified to clarify that the term refers only to the stage prior to delivery.

Paragraph (c)—No change.

Paragraph (d)—A new paragraph (d) and new definition of ''neonate'' is added.

Paragraph (d)—Paragraph (d) is relabeled paragraph (e). The definition of ''nonviable fetus'' in new paragraph (e) is modified by changing the word ''fetus'' to ''neonate.''

Paragraphs (e) and (f) are relabeled paragraphs (f) and (g).

Paragraph (g)—Paragraph (g) is relabeled paragraph (h). The definition of ''viable'' in new paragraph (h) is modified by changing the word ''fetus'' to ''neonate'' and deleting the language ''after delivery.'' Language regarding the application of Subpart D of the human subjects regulations is clarified.

Section 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization

The title of this section is changed to add the term ''neonate.''

Section 46.204 Research involving pregnant women or fetuses prior to delivery

The words ''prior to delivery'' are deleted from the title and introductory text. This description is not needed in light of the change in the definition of the term ''fetus'' in Section 46.202(b).

Paragraph (b)—The paragraph is clarified to explain that research involving fetuses may only be conducted when risk is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus, or, if there is no such prospect of benefit, the risk is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. This change is consistent with language in the January rule regarding research involving neonates that is not greater than minimal risk.

Paragraph (c)—No change.

Paragraph (d)—The paragraph is modified to clarify that if the research holds out the prospect of direct benefit to the pregnant woman, only her consent must be obtained, consistent with provisions of Subpart A of the human subjects protection regulations. The phrases ''or the consent of her legally authorized representative'' and ''unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d)'' are deleted to avoid redundancy, as these provisions are incorporated by the reference to subpart A.

A new paragraph (e) is added to clarify that if the research holds out the prospect of direct benefit solely to the fetus, the consent of the father (when the father is readily available) is required, consistent with provisions of Subpart A of the human subjects protection regulations. The father's consent is not required if he is unable to consent because of unavailability, incompetence, or temporary incapacity. Consent of the father's legally authorized representative thus would not be required under this provision. This revision changes the January rule, which allowed the mother alone to consent to research involving the fetus. We believe that this revision better recognizes the joint interests of a mother and father in a fetus's participation in research in the situation in which the research holds out the prospect of direct benefit solely to the fetus.

Paragraph (e) is relabeled paragraph (f) and new paragraph (f) is modified by replacing the language ''the woman or her legally authorized representative'' with ''the individual(s) providing consent under paragraph (d) or (e) under this section'' to take into account new Section 46.204(e).

Paragraphs (f)–(i) are relabeled paragraphs (g)–(j), and in new paragraph (j) the term ''fetus'' is changed to ''neonate.''

Section 46.205 Research involving fetuses after delivery

The title is modified by changing ''fetus'' to ''neonate'' and by deleting the words ''after delivery'' which are not needed due to the new definition of ''neonate'' provided under Section 46.202(d).

Paragraph (a)—The term ''fetus'' is changed to ''neonate'' throughout the paragraph. The words ''after delivery'' are deleted, as they are not needed due to the new definition of ''neonate'' provided under Section 46.202(d). The words ''or resultant child'' are deleted from subparagraph (2) as they are not needed due to clarifications to Section 46.202(g) described above.

Paragraph (b)—The term ''fetus'' is changed to ''neonate'' and the words ''after delivery'' are deleted throughout the paragraph. In subparagraph (1), the word ''that'' replaces ''the,'' and the words ''of the research'' are deleted to clarify that research involving risk is permitted on fetuses of uncertain viability only when it is intended to increase the probability of their survival to the point of viability. This modification is consistent with the January rule, but clarifies any ambiguity that may have been raised by minor changes to this section in that rule. In subparagraph (2), the phrase ''unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d)'' is deleted to avoid redundancy, as these provisions are incorporated by the reference to subpart A.

Paragraph (c)—The term ''fetus'' is changed to ''neonate'' throughout the paragraph.

Paragraph (d)—The term ''fetus'' is changed to ''neonate'' throughout the paragraph. Language regarding the application of Subpart D of the human subjects regulations is clarified.

Section 46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material

The term ''fetus'' is changed to ''neonate'' and the term ''fetal'' is changed to ''neonatal'' in the title.

Paragraph (a)—The term ''fetus'' is changed to ''neonate'' throughout the paragraph, and the term ''fetal is changed to ''neonatal.''

Paragraph (b)—No change.

Section 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, or fetuses

The term ''neonates'' is added to the title and throughout the section and in subparagraph (2)(iii), the phrase ''unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d)'' is deleted to avoid redundancy, as these provisions are included in the reference to subpart A.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If an action is deemed to fall within the scope of the definition of the term ''significant regulatory action'' contained in Sec. 3(f) of the Order, a pre-publication review by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) is necessary. OMB deemed this rule a ''significant regulatory action,'' as defined by Executive Order 12866. Therefore, the rule was submitted to OIRA for review prior to its publication in the **Federal Register.**

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. Chapter 6) requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. This rule primarily affects individual research subjects and institutions that receive funding from DHHS for research involving human subjects. It will not have the effect of imposing significant additional costs on small research institutions that are within the definition of small entities. Therefore, the Secretary certifies that this rule will not have significant impact on a substantial number of small entities and that preparation of an initial regulatory flexibility analysis is not required.

Paperwork Reduction Act

This rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

List of Subjects in 45 CFR Part 46

Civil rights, Health—clinical research, Human research subjects, Infants and children, Medical research, Reporting and recordkeeping requirements.

Dated: June 13, 2001.

Arthur J. Lawrence,

Acting Principal Deputy Assistant Secretary for Health.

Dated: June 14, 2001.

Tommy G. Thompson,

Secretary of Health and Human Services.

For the reasons presented in the preamble, it is proposed to amend part 46 of title 45 of the Code of Federal Regulations as set forth below.

PART 46—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for part 46 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

2. Subpart B of part 46 is revised to read as follows:

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, and Pertaining to Human In Vitro Fertilization

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, and Pertaining to Human In Vitro Fertilization

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women or human fetuses or neonates, and to all research involving the in vitro fertilization of human ova, conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of § 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in § 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Dead neonate* means a neonate that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) *Delivery* means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) *Fetus* means the product of conception from implantation until delivery.

(d) *In vitro fertilization* means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

(e) *Neonate* means a newborn.

(f) *Nonviable neonate* means a neonate after delivery that, although living, is not viable.

(g) *Pregnancy* encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(h) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(i) *Viable,* as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of Subparts A and D of this part.

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, neonates, and human in vitro fertilization.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§ 46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman or a direct benefit both to the pregnant woman and the fetus, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity;

(f) The individual(s) providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in § 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§ 46.205 Research involving neonates.

(a) Neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) The individual(s) providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(4) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(5) Individuals engaged in the research will have no part in determining the viability of a neonate.

(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part.

(c) Nonviable neonates. After delivery, a nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5). The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead neonate, or neonatal material.

(a) Research involving, after delivery, the placenta; the dead neonate; macerated neonatal material; or cells, tissue, or organs excised from a dead neonate, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

[FR Doc. 01–16841 Filed 7–5–01; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH96

Endangered and Threatened Wildlife and Plants; Availability of Draft Environmental Assessment on Proposed Designation of Critical Habitat for the Northern Great Plains Breeding Population of the Piping Plover

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service announce the availability of the draft Environmental Assessment for the proposal to designate critical habitat for the northern Great Plains breeding population of the piping plover (*Charadrius melodus*), under the Endangered Species Act of 1973, as amended. We invite all interested parties to comment on the draft Environmental Assessment and any other aspect of the proposed designation.

DATES: The comment period for the draft Environmental Assessment will close on August 13, 2001. Any comments that are received after the closing date may not be considered in the final decision on this proposal.

ADDRESSES: You may submit written comments and information to Piping Plover Comments, South Dakota Ecological Services Field Office, U.S. Fish and Wildlife Service, 420 South Garfield Avenue, Suite 400, Pierre, South Dakota 57501 or by facsimile to 605–224–9974.

You may hand-deliver written comments to our South Dakota Field Office at the address given above.

You may send comments by electronic mail (e-mail) to FW6_PipingPlover@fws.gov. See the Public Comments Solicited section below for file format and other information on electronic filing.

Copies of the draft Environmental Assessment for the northern Great Plains breeding population of the piping plover are available from the aforementioned address or on the Internet at http://mountain-prairie.fws.gov/pipingplover/ch.

You may view comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, by appointment,