

**SUMMARY:** The Food and Drug Administration (FDA) is extending until April 14, 1999, the comment period for the draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." FDA published a notice of availability of the draft guidance in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to requests for an extension.

**DATES:** Written comments on the draft guidance may be submitted by April 14, 1999. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3500, or George Q. Mills, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5097.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR

28301), for in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

In a notice published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999.

At a January 25, 1999, public meeting on the draft guidance requested by the Council on Radionuclides and Radiopharmaceuticals (CORAR), a representative of Bracco Diagnostics Inc. (Bracco) requested that FDA extend the comment period on the draft guidance to allow manufacturers of contrast media to attempt to reach consensus and submit comments on the draft guidance. On January 27, 1999, FDA received letters from Bracco and from CORAR's legal counsel requesting that the agency extend the comment period.

In response to these requests, FDA has decided to extend the comment period on the draft guidance until April 14, 1999, to allow the public more time to review and comment on its contents. FDA also intends to hold another public meeting to discuss the draft guidance prior to the close of the comment period.

Interested persons may, on or before April 14, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 1999.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF JUSTICE

### Office of the Attorney General

#### 28 CFR Part 25

[A.G. Order No. 2206-99]

RIN 1105-AA56

#### Regulations Under the Pam Lychner Sexual Offender Tracking and Identification Act of 1996, as Amended

**AGENCY:** Office of the Attorney General, Department of Justice.

**ACTION:** Proposed rule.

**SUMMARY:** The United States Department of Justice is publishing proposed regulations to implement the Pam Lychner Sexual Offender Tracking and Identification Act of 1996, as amended. The proposed regulations describe the operation of the National Sex Offender Registry and set forth notification requirements to be followed by registered sex offenders who move to another state.

**DATES:** Submit comments on or before April 19, 1999.

**ADDRESSES:** Send comments to the Unit Chief, Office of Crimes Against Children, Federal Bureau of Investigation, 935 Pennsylvania Avenue, N.W., Room 4127, Washington, DC 20535.

**FOR FURTHER INFORMATION CONTACT:** Venetia Sims, Criminal Justice Information Systems Division, Federal Bureau of Investigation, 1000 Custer Hollow Road, Clarksburg, West Virginia, 26306.

**SUPPLEMENTARY INFORMATION:** The proposed regulations address two topics: (1) The operation of the National Sex Offender Registry ("NSOR") established by the Federal Bureau of Investigation ("FBI") in accordance with Pam Lychner Sexual Offender Tracking and Identification Act of 1996, Pub. L. 104-236, 110 Stat. 3093, as amended (the "Pam Lychner Act" or the "Act"); and (2) the action required of registered sex offenders who move to another state. With respect to the NSOR, the regulations describe how the interim and permanent registries will operate and what action can be taken by states to notify the FBI and update the NSOR if a convicted sex offender fails to comply with his or her state registration obligations. With respect to offenders who move interstate, the regulations notify such offenders that they should contact the local FBI office in their new state of residence so that the FBI can take the steps necessary to ensure that the new state of residence has also been

informed of the move and that the offender is included in the NSOR.

In a recent amendment, the Pam Lychner Act was modified so that states have additional time to establish "minimally sufficient" sex offender registration programs. As a result, the proposed regulations do not address FBI registration of sex offenders in states that do not have minimally sufficient programs.

The proposed regulations also do not address the Pam Lychner Act's amendments to prior legislation, the Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act, Pub. L. 103-322, § 170101, 108 Stat. 1796, 2038 (codified at 42 U.S.C. 14071) (the "Jacob Wetterling Act"), which sets standards for state sex offender registration programs. On January 5, 1999, the Department published guidelines for the Jacob Wetterling Act (see 64 FR 572), that take those amendments into account.

#### Statutory Authority

The proposed regulations fulfill a statutory directive to the Attorney General in section 9 of the Pam Lychner Act to issue regulations to carry out the Act and the amendments made by the Act. The Pam Lychner Act amended subtitle A of title XVII of the Violent Crime Control and Law Enforcement Act of 1994 to add a new section, codified at 42 U.S.C. 14072. Since its enactment, the Pam Lychner Act has itself been amended, by section 115 of the General Provisions of Title I of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1998, Pub. L. 105-119, 111 Stat. 2440 (the "CJSA"). These proposed regulations relate to the amended provisions of the Pam Lychner Act that are now in effect.

#### Executive Order 12866

The proposed regulations have been drafted and reviewed in accordance with Executive Order 12866. The Department of Justice has determined that the proposed regulations do not constitute a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and accordingly the proposed regulations have not been reviewed by the Office of Management and Budget.

#### Executive Order 12612

The proposed regulations will not have substantial direct effect on states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various

levels of government. Therefore, in accordance with Executive Order 12612, it is determined that these rules do not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed these proposed regulations and by approving them certifies that the regulations will not have a significant economic impact on a substantial number of small entities for the following reasons. The proposed regulations primarily address the operation of the NSOR established by the FBI. Recent amendments to the Jacob Wetterling Act in section 115 of the CJSA condition the receipt of certain federal funds on a state's participation in the NSOR. In order to impose the least financial burden on participating states, the FBI allows them to provide data for the NSOR in three ways: (1) By making a computer entry on the existing Interstate Identification Index ("III"); (2) by submitting a computer tape to the FBI; or (3) by submitting a written form containing all the necessary registration information. In addition, in order to facilitate broad participation in the NSOR, the FBI permits—but does not require—authorized local government agencies to enter, delete, and modify information in the registry using the III, as long as the state has implemented the necessary programming changes. This option allows those small government entities that provide data to the NSOR to do so in the most cost-effective manner possible.

#### Unfunded Mandates Reform Act of 1995

As noted, recent amendments in the CJSA to the Jacob Wetterling Act make state participation in the NSOR a condition of receipt of certain federal funds. As a result, these regulations do not impose a "federal mandate" within the meaning of the Unfunded Mandates Reform Act of 1995. Moreover, these regulations will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandate Reform Act.

#### Small Business Regulatory Enforcement Fairness Act of 1996

These regulations do not qualify as a major rule as defined by the Small Business Regulatory Enforcement

Fairness Act of 1996, 5 U.S.C. 804. The regulations will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### Amendments to the Pam Lychner Act

Under the Pam Lychner Act, the FBI is required to register sex offenders who reside in states that have not established "minimally sufficient" sex offender registration systems. The CJSA amended the criteria that state registration programs must satisfy in order to qualify as minimally sufficient and extended the time period for states to establish such programs. As assessment of minimal sufficiency to determine in which states the FBI must directly register sex offenders will be made by the extended date for establishing a minimally sufficient program provided under the CJSA, October 3, 1999.

#### Amendments to the Jacob Wetterling Act

The Pam Lychner's Act amendments to the Jacob Wetterling Act, which set standards for state sex offender registration programs, are not addressed in these regulations. The Department of Justice has published guidelines under the Jacob Wetterling Act, see 64 FR 572, that take account of the Pam Lychner Act's changes and subsequent amendments.

#### List of Subjects in Part 25

Crime, Law enforcement.

#### Proposed Regulations

For the reasons stated in the preamble, the Department of Justice proposes to amend 28 CFR by adding part 25, subpart B, to read as follows:

#### PART 25—DEPARTMENT OF JUSTICE INFORMATION SYSTEMS

##### Subpart B—The National Sex Offender Registry

- Sec.
- 25.200 The interim sex offender registry.
  - 25.201 The permanent sex offender registry.
  - 25.202 Release of information from the National Sex Offender Registry.
  - 25.203 Non-compliant offenders.
  - 25.204 Notice of an offender's move to another state.

### Subpart B—The National Sex Offender Registry

**Authority:** 42 U.S.C. 14072; Pub. L. 104–236, 110 Stat. 3093; Pub. L. 105–119, sec. 115, 111 Stat. 2440, 2461.

#### § 25.200 The interim sex offender registry.

(a) The Pam Lychner Act, 42 U.S.C. 14072(b), requires the Attorney General to establish a national database at the FBI to track the whereabouts and movement of:

(1) Each person who has been convicted of a criminal offense against a victim who is a minor, as defined in 42 U.S.C. 14071(a)(3)(A);

(2) Each person who has been convicted of a sexually violent offense, as defined in 42 U.S.C. 14071(a)(3)(B); and

(3) Each person who is a sexually violent predator, as defined in 42 U.S.C. 14071(a)(3)(C).

(b) In accordance with section 2 of the Pam Lychner Act, the Federal Bureau of Investigation (“FBI”) has established an interim National Sex Offender Registry (the “Interim Registry”) in the Fingerprint Identification Records System (“FIRS”).

(c) The Interim Registry functions as a “pointer” system, indicating on an individual’s FBI Identification Record the fact that the individual is a registered sex offender and the name and location of the state agency that maintains the offender’s registration information.

(d) States may participate in the Interim Registry by submitting the following information to the FBI pertaining to individuals who are registered in state sex offender registries: the name under which the person is registered; the registering agency’s name and location; the date of registration; and the date registration expires. A notice indicating that an individual is a registered sex offender and listing the information described in this paragraph will be included on the individual’s FBI Identification Record. In order to obtain more detailed information regarding a particular offender, an inquiring agency must contact the registering agency indicated on the FBI Identification Record.

#### § 25.201 The permanent sex offender registry.

(a) The FBI is in the process of modifying and improving its National Crime Information Center (“NCIC”) to establish a new crime information system that will be known as “NCIC 2000.” NCIC 2000, which is expected to go online in mid-1999, will include a Convicted Sexual Offender Registry File that will serve as the permanent

National Sex Offender Registry (the “Permanent Registry”).

(b) In the Permanent Registry, sex offender registration information will be entered directly, via the NCIC Convicted Sexual Offender Registry File by federal, state, and local law enforcement agencies, and will include such information as the offender’s name, address, and details regarding the conviction resulting in registration. This detailed information will be available to authorized agencies via the NCIC. The sex offender registration information will also be automatically posted to the individual’s FBI Identification Record.

#### § 25.202 Release of information from the National Sex Offender Registry.

(a) The Pam Lychner Act, 42 U.S.C. 14072(j), requires the FBI to release the information contained in the National Sex Offender Registry to:

(1) Federal, state, and local criminal justice agencies for law enforcement purposes and community notification; and

(2) Federal, state, and local governmental agencies responsible for conducting employment-related background checks under the National Child Protection Act, 42 U.S.C. 5119a.

(b) Both the Interim and Permanent Registries are available for these purposes.

#### § 25.203 Non-compliant offenders.

(a) The Pam Lychner Act, 42 U.S.C. 14072(g)(5), provides for state notification to the FBI if a state cannot verify the address of or locate a person required to register with the state’s registration program. The Act further provides that once the FBI receives such a notification, the FBI shall classify the offender as being in violation of the requirements of the National Sex Offender Registry and add a Wanted Person record to the NCIC Wanted Person File, provided that an arrest warrant meeting the requirements for entry into that File is issued in connection with the violation.

(b) The purpose of the requirement that states notify the FBI of non-compliant offenders is to permit the FBI to indicate on the national system that a sex offender is not complying with his or her registration obligations. States can comply with the notice requirement by obtaining an arrest warrant for non-compliant offenders and entering records for such offenders into the Wanted Person File, as described in paragraph (c) of this section. Upon entry of a wanted person record on the Wanted Person File, that fact will automatically be indicated on the offender’s FBI Identification Record and

will be accessible on a search of the National Sex Offender Registry.

(c) Under existing FBI procedures, state and local law enforcement authorities add records of fugitives to the NCIC Wanted Person File upon issuance of a state or local arrest warrant. The FBI will continue to follow those same procedures with respect to registered sex offenders. Accordingly, if an offender fails to comply with a state registration program requirement, state or local authorities should, if appropriate, seek an arrest warrant for that offender and then add a record for the offender to the NCIC Wanted Person File.

#### § 25.204 Notice of an offender’s move to another state.

The Pam Lychner Act, 42 U.S.C. 14072(g), requires an offender who moves to a different state to notify both the FBI and the new state of residence so that his or her registration information may be included in the appropriate state and federal databases. No later than 10 days after the offender establishes a new residence, the offender should contact the local FBI office in his or her new state of residence. Once notified by an offender that he or she has moved to another state, the FBI will take the steps necessary to ensure that the offender’s new state of residence has also been notified.

Dated: February 9, 1999.

**Janet Reno,**

*Attorney General.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[FRL–6301–2]

### National Priorities List for Uncontrolled Hazardous Waste Sites, Proposed Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA” or “the Act”), requires that the National Oil and Hazardous Substances Pollution Contingency Plan (“NCP”) include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (“NPL”)