

how the agency will interpret and apply provisions of the existing regulations regarding the content and format of an application for approval of a new drug (21 CFR 314.50) and the content of a biological product application (21 CFR 601.25). In addition, the draft guidance provides information on how the agency will interpret and apply the proposed rule on the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring (63 FR 28301). The proposed rule, by adding part 315, would clarify existing FDA requirements for the evaluation and approval of drug and biological radiopharmaceuticals already in place under the authority of the act and the PHS Act.

Existing regulations, which appear primarily in parts 314 and 601 (21 CFR parts 314 and 601), specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of new drugs and biological products. This information is usually submitted as part of a new drug application (NDA) or a biologics license application (BLA), or as a supplement to an approved application. This draft guidance supplements these regulations. Under the proposed rule and the draft guidance, information required under the act and the PHS Act and needed by

FDA to evaluate safety and effectiveness would still have to be reported.

**Description of Respondents:** Manufacturers of medical imaging drugs and biologics, including contrast drug products and diagnostic radiopharmaceuticals.

**Burden Estimate:** The proposed rule on in vivo radiopharmaceuticals used for diagnosis and monitoring sets forth an estimated annual reporting burden on the industry that would result from that rulemaking (63 FR 28301 at 28305 to 28306). This draft guidance on the development of medical imaging drugs and biologics is in part intended to explain how FDA will interpret and apply the proposed rule. Thus, the estimated annual reporting burden of the draft guidance, as provided in the chart below, is the same as that of the proposed rule, with one change. In addition to the diagnostic radiopharmaceuticals that are the subject of the proposed rule, the draft guidance also addresses the development of contrast drug products, which FDA evaluates and approves under part 314, but which are not affected by the proposed rule.

The chart below provides an estimate of the annual reporting burden for diagnostic radiopharmaceuticals and is based on the estimate described in the proposed rule (63 FR 28301 at 28306). The chart also provides an estimate for

the annual reporting burden for contrast drug products. FDA estimates that the potential number of respondents who would submit applications or supplements for contrast drug products would be one. Although FDA did not approve any NDA's for contrast drugs (there are no biological contrast drug products) in fiscal year 1997 (FY 1997), for purposes of estimating the annual reporting burden, the agency assumes that it will approve one contrast drug each fiscal year. The annual frequency of responses for contrast drugs is estimated to be one response per application or supplement. The hours per response, which is the estimated number of hours that an applicant would spend preparing the information to be submitted for a contrast drug in accordance with this draft guidance, is estimated to be approximately 2,000 hours.

The draft guidance would not impose any additional reporting burden because safety and effectiveness information is already required by existing regulations. In fact, clarification by the draft guidance of FDA's standards for evaluation of medical imaging drugs and biologics is expected to reduce the overall burden of information collection. FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| No. of Respondents              | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |        |
|---------------------------------|-------------------------------|------------------------|--------------------|-------------|--------|
| Diagnostic Radiopharmaceuticals | 8                             | 1                      | 8                  | 2,000       | 16,000 |
| Contrast Drugs                  | 1                             | 1                      | 1                  | 2,000       | 2,000  |
| Total                           |                               |                        |                    |             | 18,000 |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by November 13, 1998, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

#### IV. Electronic Access

An electronic version of this draft guidance document is available on the Internet using the World Wide Web (WWW) at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm".

Dated: October 6, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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#### DEPARTMENT OF JUSTICE

##### Office of Juvenile Justice and Delinquency Prevention

#### 28 CFR Part 31

[OJP (OJJDP)—1158]

RIN 1121-AA46

#### Juvenile Accountability Incentive Block Grants

**AGENCY:** Office of Juvenile Justice and Delinquency Prevention (OJJDP), Office of Justice Programs, Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes procedures under which an eligible State, or unit of local government that receives a subgrant from the State, is

required to provide notice to the Attorney General regarding the proposed use of funds available under the Juvenile Accountability Incentive Block Grants (JAIBG) program, a new block grant program designed to promote greater accountability in the juvenile justice system. The Attorney General, through the Assistant Attorney General for the Office of Justice Programs (OJP), has delegated the authority to administer the JAIBG program to the Administrator of the Office of Juvenile Justice and Delinquency Prevention.

**DATES:** Comments will be received no later than November 13, 1998.

**ADDRESSES:** Comments should be sent to: Shay Bilchik, Administrator, Office of Juvenile Justice and Delinquency Prevention, 810 7th Street, NW, Washington, DC 20531.

**FOR FURTHER INFORMATION CONTACT:** Rodney L. Albert, Deputy Director, State Relations and Assistance Division, OJJDP, 810 7th Street, NW, Washington, DC 20531. Phone: (202) 307-5924.

**SUPPLEMENTARY INFORMATION:** Public Law 105-119, November 26, 1997, Making Appropriations for the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies for the Fiscal Year Ending September 30, 1998, and for other Purposes (Appropriations Act) appropriated \$250,000,000 for the Juvenile Accountability Incentive Block Grants (JAIBG) program described in Title III of H.R. 3, as passed by the House of Representatives on May 8, 1997.

Funds are available under JAIBG in FY 1998 for State and local grants to support the following program purposes as set forth in Section 1801(b)(1)-(11) of H.R. 3:

(1) Building, expanding, renovating, or operating temporary or permanent juvenile correction or detention facilities, including the training of correctional personnel;

(2) Developing and administering accountability-based sanctions for juvenile offenders;

(3) Hiring additional juvenile judges, probation officers, and court-appointed defenders, and funding pre-trial services for juveniles, to ensure the smooth and expeditious administration of the juvenile justice system;

(4) Hiring additional prosecutors, so that more cases involving violent juvenile offenders can be prosecuted and backlogs reduced;

(5) Providing funding to enable prosecutors to address drug, gang, and youth violence more effectively;

(6) Providing funding for technology, equipment, and training to assist prosecutors in identifying and expediting the prosecution of violent juvenile offenders;

(7) Providing funding to enable juvenile courts and juvenile probation offices to be more effective and efficient in holding juvenile offenders accountable and reducing recidivism;

(8) The establishment of court-based juvenile justice programs that target young firearms offenders through the establishment of juvenile gun courts for the adjudication and prosecution of juvenile firearms offenders;

(9) The establishment of drug court programs for juveniles so as to provide continuing judicial supervision over juvenile offenders with substance abuse problems and to provide the integrated administration of other sanctions and services;

(10) Establishing and maintaining interagency information sharing programs that enable the juvenile and criminal justice system, schools, and social services agencies to make more informed decisions regarding the early identification, control, supervision, and treatment of juveniles who repeatedly commit serious delinquent or criminal acts;

(11) Establishing and maintaining accountability-based programs that work with juvenile offenders who are referred by law enforcement agencies, or which are designed, in cooperation with law enforcement officials, to protect students and school personnel from drug, gang, and youth violence; and,

(12) Implementing a policy of controlled substance testing for appropriate categories of juveniles within the juvenile justice system.

Eligible applicants in FY 1998 are States whose Governor (or other Chief Executive Officer for the eligible jurisdictions that are not one of the 50 States but defined as such for purposes of this program under § 1808(3) of Title III of H.R. 3) certifies, consistent with guidelines established by the Attorney General in consultation with Congress and incorporated into OJJDP's Program Guidance Manual, that the State is actively considering (or already has in place), or will consider within one year from the date of such certification, legislation, policies, or practices which, if enacted, would qualify the State for a grant under Section 1802 of H.R. 3. Specific information regarding Section 1802 qualifications can be found in the JAIBG Program Guidance Manual.

The Chief Executive of each State is required to designate a State agency to apply for, receive, and administer JAIBG funds. The designated State agency will

administer funds allocated to the State based on relative population of people under 18 years of age, with no more than 25% of the funds retained at the State level, absent a waiver, and with 75% or more allocated and subgranted to units of local government within the State. Specific information regarding "waiver" qualifications can be found in the JAIBG Program Guidance Manual.

JAIBG funds awarded to a State and expended at the State level or subgranted by a State to a unit of local government, other than funds set aside for administrative costs, may be expended only for programs or projects under one or more of the twelve purpose areas established by law.

Detailed information regarding all other requirements of the JAIBG program is available to eligible applicants in OJJDP's JAIBG Program Guidance Manual. The manual is available on the OJJDP homepage at [www.ncjrs.org/ojjhome.htm](http://www.ncjrs.org/ojjhome.htm).

#### **Executive Order 12866**

This proposed regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Office of Justice Programs has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

#### **Executive Order 12612**

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

#### **Regulatory Flexibility Act**

The Office of Justice Programs, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities for the following reasons:

(1) The proposed Rule provides the procedures under which eligible applicants are required to provide notice regarding the proposed use of funds available under the JAIBG program; and

(2) The award of such funds imposes no requirements on small business or on small entities.

#### **Unfunded Mandates Reform Act of 1995**

This rule 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 it will not uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

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

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete in domestic and export markets.

#### **National Environmental Policy Act**

This proposed rule has been reviewed in accordance with OJP's Procedures for Implementing the National Environmental Policy Act, 28 CFR Part 61. The Assistant Attorney General for OJP has determined that this regulation does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91-190, an Environmental Impact Statement is not required.

#### **Paperwork Reduction Act**

The collection of information requirements contained in this proposed regulation will be submitted to the Office of Management and Budget for review under the Paperwork Reduction Act (44 U.S.C. 3504(h)).

#### **List of Subjects in 28 CFR Part 31**

Grant programs—law, Juvenile delinquency, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 28 CFR Part 31 is proposed to be amended as follows:

#### **PART 31—OJJDP GRANT PROGRAMS**

1. The Heading for Part 31 is revised as set forth above.
2. The authority citation for Part 31 is revised to read as follows:

**Authority:** 42 U.S.C. 5601 *et seq.*; Pub.L. 105-119, 111 Stat. 2440.

3. The designations "Subpart A" through "Subpart E" are removed and the headings remain as undesignated centerheadings.

4. Sections 31.1 through 31.403, and the undesignated centerheadings, are designated as Subpart A and a new subpart heading is added to read as follows:

##### **Subpart A—Formula Grants**

5. Section 31.1 is amended by revising "This part" to read "This subpart".

6. Part 31 is amended by adding a new Subpart B consisting of §§ 31.500 through 31.503 to read as follows:

##### **Subpart B—Juvenile Accountability Incentive Block Grants**

Sec.

- 31.500 Program purposes.
- 31.501 Eligible applicants.
- 31.502 Assurances and plan information.
- 31.503 Notice of proposed use of funds.

##### **Subpart B—Juvenile Accountability Incentive Block Grants**

###### **§ 31.500 Program purposes.**

Funds are available under the Juvenile Accountability Incentive Block Grants (JAIBG) in FY 1998 for State and local grants to support the following program purposes:

- (a) Building, expanding, renovating, or operating temporary or permanent juvenile correction or detention facilities, including the training of correctional personnel;
- (b) Developing and administering accountability-based sanctions for juvenile offenders;
- (c) Hiring additional juvenile judges, probation officers, and court-appointed defenders, and funding pre-trial services for juveniles, to ensure the smooth and expeditious administration of the juvenile justice system;
- (d) Hiring additional prosecutors, so that more cases involving violent juvenile offenders can be prosecuted and backlogs reduced;
- (e) Providing funding to enable prosecutors to address drug, gang, and youth violence more effectively;
- (f) Providing funding for technology, equipment, and training to assist prosecutors in identifying and expediting the prosecution of violent juvenile offenders;
- (g) Providing funding to enable juvenile courts and juvenile probation offices to be more effective and efficient in holding juvenile offenders accountable and reducing recidivism;
- (h) The establishment of court-based juvenile justice programs that target

young firearms offenders through the establishment of juvenile gun courts for the adjudication and prosecution of juvenile firearms offenders;

(i) The establishment of drug court programs for juveniles so as to provide continuing judicial supervision over juvenile offenders with substance abuse problems and to provide the integrated administration of other sanctions and services;

(j) Establishing and maintaining interagency information sharing programs that enable the juvenile and criminal justice system, schools, and social services agencies to make more informed decisions regarding the early identification, control, supervision, and treatment of juveniles who repeatedly commit serious delinquent or criminal acts;

(k) Establishing and maintaining accountability-based programs that work with juvenile offenders who are referred by law enforcement agencies, or which are designed, in cooperation with law enforcement officials, to protect students and school personnel from drug, gang, and youth violence; and

(l) Implementing a policy of controlled substance testing for appropriate categories of juveniles within the juvenile justice system.

###### **§ 31.501 Eligible applicants.**

(a) *Eligible applicants.* Eligible applicants in FY 1998 are States whose Governor (or other Chief Executive Officer for the eligible jurisdictions that are not one of the 50 States but defined as such for purposes of this program) certifies, consistent with guidelines established by the Attorney General in consultation with Congress and incorporated into OJJDP's Program Guidance Manual, that the State is actively considering (or already has in place), or will consider within one year from the date of such certification, legislation, policies, or practices which, if enacted, would qualify the State for a grant. Specific information regarding qualifications can be found in the JAIBG Program Guidance Manual (which can be obtained from the Juvenile Justice Clearinghouse at 1-800-638-8736 or on the OJJDP homepage at [www.ncjrs.org/ojjhome.htm](http://www.ncjrs.org/ojjhome.htm)).

(b) *Qualifications.* Each State Chief Executive Officer must designate a state agency to apply for, receive, and administer JAIBG funds.

###### **§ 31.502 Assurances and plan information.**

(a) In its application for a Juvenile Accountability Incentive Block Grant (JAIBG), each State must provide assurances to the Office of Juvenile Justice and Delinquency Prevention

(OJJDP), absent a waiver as provided in the JAIBG Program Guidance Manual, that:

(1) The State will subgrant at least 75% of the State's allocation of funds to eligible units of local government to implement authorized programs at the local level; and

(2) The State, and each unit of local government applying for a subgrant from the State, will expend not less than 45% of any grant provided to such State or unit of local government, other than funds set aside for administration, for program purposes 3–9 set forth in § 31.500 of this subpart, and will not spend less than 35% for program purposes 1, 2, and 10 set forth in § 31.500 of this subpart, unless the State certifies to OJJDP, or the unit of local government certifies to the State, that the interests of public safety and juvenile crime control would be better served by expending the grant award for purposes set forth in the twelve program areas in a different ratio. Such certification shall provide information concerning the availability of existing structures or initiatives within the intended areas of expenditure (or the availability of alternative funding sources for those areas), and the reasons for the State or unit of local government's alternative use.

(b) Following award of JAIBG funds to a State by OJJDP, but prior to obligation of program funds by the State or of subgrant funds by a unit of local government for any authorized program purpose, a State administering JAIBG funds must provide to OJJDP information that demonstrates that the State, or a unit of local government that receives JAIBG funds, has established a coordinated enforcement plan for reducing juvenile crime, developed by a Juvenile Crime Enforcement Coalition (JCEC).

(c) State coordinated enforcement plans must be developed by a Juvenile Crime Enforcement Coalition consisting of representatives of law enforcement and social service agencies involved in juvenile crime prevention. To assist in developing the State's coordinated enforcement plan, States may choose to utilize members of the State Advisory Group (SAG) established by the State's Chief Executive under Section 223(a)(3) of Part B of the Juvenile Justice and Delinquency Prevention (JJDP) Act of 1974, as amended, codified at 42 U.S.C. 5633(a)(3), if appropriate membership exists, or use or establish another planning group that constitutes a coalition of law enforcement and social service agencies.

(d)(1) When establishing a local Juvenile Crime Enforcement Coalition

(JCEC), units of local government must include, unless impracticable, individuals representing:

(i) Police;  
(ii) Sheriff;  
(iii) Prosecutor;  
(iv) State or local probation services;  
(v) Juvenile court;  
(vi) Schools;  
(vii) Business; and (viii) Religious affiliated, fraternal, nonprofit, or social service organizations involved in crime prevention.

(2) Units of local government may utilize members of Prevention Policy Boards established pursuant to Section 505(b)(4) of Title V of the JJDP Act, codified at 42 U.S.C. 5784(b)(4), to meet the JCEC requirement, provided that each JCEC meets the membership requirements listed in paragraph (d)(1) of this section.

#### **§ 31.503 Notice of proposed use of funds.**

The mechanism for a State to report on the proposed use of funds by the State or by a subgrantee unit of local government is by electronic submission of a "Follow Up Information Form" to be provided to each participating State. Upon receipt and review of the "Follow Up Information Form" by OJJDP, States may obligate program funds retained for expenditure at the State level. Similarly, the State shall require that each recipient unit of local government submit its proposed use of non-administrative funds to the State prior to drawdown of subgrant funds to implement local programs and projects. Upon receipt and review of the local unit of government's proposed fund use, the State shall authorize the local unit of government to obligate local subgrant funds. The State shall electronically submit a copy of the local subgrant information to OJJDP, as provided in the award package, within 30 days of the date that the local unit of government is authorized to obligate program funds under its subgrant award.

**Shay Bilchik,**

*Administrator, Office of Juvenile Justice and Delinquency Prevention.*

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## **FEDERAL EMERGENCY MANAGEMENT AGENCY**

### **44 CFR Part 67**

[Docket No. FEMA–7267]

### **Proposed Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency, FEMA.

**ACTION:** Proposed rule.

**SUMMARY:** Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

**ADDRESSES:** The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

**FOR FURTHER INFORMATION CONTACT:** Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA or Agency) proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

### **National Environmental Policy Act**

This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental