

assessments.<sup>1</sup> The CJIS Division had diverted personnel from other key programs in order to finalize as many security risk assessments as possible without compromising its other missions. It is important to note that the time needed to process a security risk assessment varies in relation to the complexity of each application. Some individuals may be processed in as little as two weeks once processing begins, while other individuals can take several months. At its current processing rate, the CJIS Division expects to be able to finalize by the November 12, 2003, deadline the security risk assessments of almost all of the completed applications that were pending as of October 1, 2003.

However, in addition to the complete application packages, the CJIS Division also has received incomplete packages. The CJIS Division has sent more than 2,450 letters informing Responsible Officials of the incomplete applications of their personnel. In light of its present capacity and processing times, the CJIS Division has projected that even if immediately completed, these outstanding applications could not be processed by the November 12, 2003 regulatory deadline.

We believe that the continued operation of these facilities is vital to the public interest. We also believe that those entities and individuals that have submitted all of the required information and forms by November 12, 2003, have made a good faith effort to comply with these regulations. We are therefore amending the applicability requirements to allow for the issuance of provisional registration certificates for entities, and provisional grants of access for individuals, from whom, prior to November 12, 2003, the Attorney General has received all of the information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73. This action is necessary to ensure that, as required by the Act, ongoing research and educational efforts important to the national defense are not disrupted. We are also amending the applicability requirements to allow for the issuance of provisional registration certificates for entities not currently in possession of select agents or toxins from whom, prior to November 12, 2003, the Attorney General has received all the

information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73 and the Secretary, HHS, determines such action is in the interest of the public health and national security. An entity's provisional registration will stay in effect until the Secretary either grants the entity a certificate of registration or revokes the entity's provisional registration. An individual's provisional grant of access will remain in effect until the Secretary either grants access or revokes the individual's provisional grant of access. This action is necessary to ensure that new research, educational, and national security preparedness efforts are not impeded.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

#### Authority for Interim Final Rule

We are amending the December 2002 interim final rule to insure that the provisions of the Part 73 are consistent with the original intent of the Act. Consequently, the Act also requires this amendment to be published as an interim final rule (42 U.S.C. 262a, note). Further, pursuant to 5 U.S.C. 553, we find that notice and public procedure are impracticable, unnecessary, and contrary to the public interest and that we have good cause to dispense with notice and comment on this amendment. The amendment will prevent disruption or termination of ongoing research and educational projects by hundreds of entities and thousands of individuals needing access to select agents and toxins.

Immediate action is necessary to prevent the imposition of an unnecessary burden on the regulated community; and to ensure the appropriate availability of biological toxins for research, education, and other legitimate purposes. Under these circumstances, the Secretary has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

#### Paperwork Reduction Act

This interim final rule does not contain any new provisions constituting

a collection of information under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

#### Executive Order 12866

This interim final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

#### Regulatory Flexibility Act

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

#### Unfunded Mandates

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any given year. This interim final rule is not expected to result in any one-year expenditure that would exceed \$100 million.

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### List of Subjects in 42 CFR Part 73

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

Dated: October 30, 2003.

**Tommy G. Thompson,**  
*Secretary.*

■ For the reasons stated in the preamble, 42 CFR part 73 is amended as follows:

■ 1. The authority citation for Part 73 continues to read as follows:

**Authority:** 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

#### § 73.0 [Amended]

■ 2. Amend § 73.0 by adding paragraphs (b)(5), through (b)(8) and paragraphs (c)(5) through (c)(8) to read as follows:

<sup>1</sup> To avoid delays related to incomplete applications, individuals and entities should submit their FD–961 forms and fingerprint cards to the CJIS Division in one package. However, this does not apply to applicants who are submitting follow-up information or fingerprint cards for an existing incomplete application.