registration statement for bank securities submitted by such group. The PRA burden in part 16 is currently approved under OMB Control No. 1557–0120. Therefore, we submitted the entire information collection for review. The numbers below reflect the entire burden for part 16 following adoption of the rule and the review of the entire information collection to ensure accuracy of the estimates.

Title of Information Collection: Securities Offering Disclosure Rules—12 CFR Part 16.

OMB Number: 1557–0120.

Estimated Number of Respondents: 48.

Estimated Number of Responses: 48.

Average Hours per Response: 9.375.

Total Estimated Annual Burden: 450.

Affected Public: National bank charter applicants.

Estimated Net Burden Change: −60 hours.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (2 U.S.C. 1532) (Unfunded Mandates Act), requires that an agency prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year. If a budgetary impact statement is required, Section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC has determined that this proposed rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more in any one year. Accordingly, this proposal is not subject to Section 202 of the Unfunded Mandates Act.

List of Subjects in 12 CFR Part 16

National banks, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, chapter I of title 12 of the Code of Federal Regulations is proposed to be amended as follows:

PART 16—SECURITIES OFFERING DISCLOSURE RULES

1. The authority citation for part 16 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.* and 93a.

2. Add § 16.15(e) to read as follows:

§ 16.15 Form and content.

* * * * *

(e) Notwithstanding paragraph (a) of this section, an organizing group seeking to establish a national bank charter pursuant to § 5.20 of this chapter shall not be required to include audited financial statements as part of its registration statement, unless the OCC determines that factors particular to the proposal indicate that inclusion of such statements would be in the interest of investors or would further the safe and sound operation of a national bank. The term ''organizing group'' shall have the meaning set forth in § 5.20(d)(6) of this chapter.

Dated: October 12, 2007.

John C. Dugan,

Comptroller of the Currency.

[FR Doc. E7–20600 Filed 10–17–07; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. 2007N–0284]

Revision of the Requirements for Live Vaccine Processing; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by providing options to the existing requirement for the processing of live vaccines. FDA is proposing to amend the regulations due to advances in technology that will allow processing of live vaccines to be performed in multiproduct manufacturing areas. We are publishing this rule because the existing requirement regarding facilities and equipment for processing live vaccines is too prescriptive and is no longer necessary. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments or electronic comments by January 2, 2008.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0284, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- 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.

Written Submissions

Submit written submissions in the following ways:

- 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. 2007N–0284 for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments see the ''Request for Comments'' heading in section VII of 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 and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Live organisms are used in the production of certain vaccine products.

These live organisms are generally used as source material for further manufacture into final products used in the prevention, treatment, or cure of a disease or condition of human beings. Live organisms pose a challenge to manufacturers in the prevention of cross contamination of other products and manufacturing areas. Some live organisms used in manufacturing may be harmful to humans, especially immunocompromised patients. To ensure the safety of a biological product manufactured in the same building or area in which live organisms are utilized, tight controls are needed to avoid the release of any live organisms into the manufacturing environment and to prevent cross contamination of other products manufactured in the same building or area.

Current FDA regulations strictly limit how live vaccine processing may be performed. Current § 600.11(e)(4) (21 CFR 600.11(e)(4)) requires that: (1) Space used for processing a live vaccine must be decontaminated before processing is started and must not be used for any other purpose during the vaccine processing; (2) live vaccine processing areas must be isolated from and independent of any space used for any other purpose by being either in a separate building, in a separate wing of a building, or in quarters at the blind end of a corridor; (3) the processing area must include adequate space and equipment for all processing steps up to, but not including, filling into final containers; and (4) test procedures that potentially involve the presence of microorganisms other than the vaccine strains, or the use of tissue culture cell lines other than primary cultures, must not be conducted in space used for processing live vaccine.

We are proposing to revise § 600.11(e)(4) to allow greater flexibility for vaccine manufacturers regarding the buildings and equipment used for live vaccine processing. The proposed revisions provide for the use of modern manufacturing approaches to assist vaccine manufacturers who engage in live vaccine processing, e.g., manufacturers of influenza virus vaccines. The proposed revisions provide that live vaccine processing steps may be performed in multiproduct manufacturing buildings and areas when appropriate controls exist to prevent cross contamination of other products and areas. We recognize that advances in facility, utility, system, and equipment design, as well as in sterilization, decontamination, and disinfection technologies have increased the ability of manufacturers to control the manufacture of biological products and the equipment used in their manufacture. The use of appropriate controls, procedures, and processes provides an adequate degree of confidence that a product meets the expected levels of safety, purity, and potency. Areas of special concern, such as containment, decontamination, sterilization, and disinfection can be addressed using currently available controls, procedures, and processes. The scope of this regulation is limited to all live vaccine processing steps up to, but not including, filling into final containers. In section II of this document, we identify each of the changes included in this proposed rule.

II. Highlights of the Proposed Rule

We are proposing to revise § 600.11(e)(4) to require that live vaccine processing be performed under appropriate controls to prevent cross contamination of other products and other manufacturing areas within the building. We regard an area as a specific room or set of rooms within a building associated with the manufacturing of any one product or multiple products.

Proposed § 600.11(e)(4)(i) is analogous to the preexisting § 600.11(e)(4). In proposed § 600.11(e)(4)(i)(A), we provide that a manufacturer can use an area that is either in a separate building, in a separate wing of a building, or in quarters at the blind end of a corridor and includes adequate space and equipment for all processing steps up to, but not including, filling into final containers. In proposed § 600.11(e)(4)(i)(B), we require that a manufacturer not use the manufacturing space for conducting test procedures that potentially involve the presence of microorganisms other than the vaccine strains or the use of tissue culture cell lines other than primary cultures.

In proposed § 600.11(e)(4)(ii), if manufacturing is conducted in a multiproduct manufacturing building or area, we require appropriate controls including procedural controls, and where necessary, process containment, to prevent cross contamination of other products and other manufacturing areas within the building. In addition, we are requiring that all product, equipment, and personnel movement between distinct live vaccine processing areas and between live vaccine processing areas and other manufacturing areas up to, but not including, filling in containers, must be conducted under conditions that will prevent cross contamination of other products and manufacturing areas within the building, including the introduction of live vaccine organisms into these other areas. Process containment is a system designed to mechanically isolate equipment or an area that involves manufacturing using live vaccine organisms. Procedural controls establish and perform effective decontamination, sterilization, and disinfection, as well as execute manufacturing procedures in such a manner as to prevent cross contamination with live vaccine organisms.

As part of their procedural controls, manufacturers must have written procedures and effective processes in place to adequately remove or decontaminate live vaccine organisms from manufacturing areas and from equipment for subsequent manufacture of other products. Written procedures must be in place for verification that processes to remove or decontaminate live vaccine organisms have been followed. All potential routes of cross contamination to other manufacturing areas should be addressed, including movement of persons (e.g., technical, maintenance, delivery, management personnel, and visitors), equipment, and in-process materials. Live vaccine organisms should not be removed from designated areas unless this can be done in a manner that prevents the cross contamination of other products and manufacturing areas. These procedural controls will provide a level of assurance that products made in areas where live vaccines are manufactured remain safe, pure, and potent.

III. Legal Authority

FDA is issuing this regulation under the biological products provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264), and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351–353, 355, 360, 371, and 374). Under these provisions of the PHS Act and the act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, effective, pure, and potent, and to prevent the introduction, transmission, and spread of communicable disease.

IV. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments

received under this companion proposed rule will also be considered as comments regarding the direct final rule. We are publishing the direct final rule because the rule is noncontroversial, and we do not anticipate that it will receive any significant adverse comments.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this companion proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on March 18, 2008. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

V. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not an economically significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would provide increased flexibility for the processing of live vaccines, it would decrease overall compliance costs. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1–year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

C. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. The Paperwork Reduction Act of 1995

This proposed rule contains no new collections of information. The collection of information under § 600.11(e)(4) is covered by OMB control numbers 0910–0139 (expires September 30, 2008) and 0910–0308 (expires July 31, 2008). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 600 be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

2. Section 600.11 is amended by revising paragraph (e)(4) to read as follows:

§ 600.11 Physical establishment, equipment, animals, and care.

* * * * *

(e) * * *

(4) *Live vaccine processing.* Live vaccine processing must be performed under appropriate controls to prevent cross contamination of other products and other manufacturing areas within the building. Appropriate controls must include, at a minimum:

(i)(A) Using a dedicated manufacturing area that is either in a

separate building, in a separate wing of a building, or in quarters at the blind end of a corridor and includes adequate space and equipment for all processing steps up to, but not including, filling into final containers; and

(B) Not conducting test procedures that potentially involve the presence of microorganisms other than the vaccine strains or the use of tissue culture cell lines other than primary cultures in space used for processing live vaccine; or

(ii) If manufacturing is conducted in a multiproduct manufacturing building or area, using procedural controls, and where necessary, process containment. Process containment is deemed to be necessary unless procedural controls are sufficient to prevent cross contamination of other products and other manufacturing areas within the building. Process containment is a system designed to mechanically isolate equipment or an area that involves manufacturing using live vaccine organisms. All product, equipment, and personnel movement between distinct live vaccine processing areas and between live vaccine processing areas and other manufacturing areas, up to, but not including, filling in final containers, must be conducted under conditions that will prevent cross contamination of other products and manufacturing areas within the building, including the introduction of live vaccine organisms into other areas. In addition, written procedures and effective processes must be in place to adequately remove or decontaminate live vaccine organisms from the manufacturing area and equipment for subsequent manufacture of other products. Written procedures must be in place for verification that processes to remove or decontaminate live vaccine organisms have been followed.

* * * * *

Dated: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–20609 Filed 10–17–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 522, 559 and 573

RIN 3141–AA23

Facility License Standards

AGENCY: National Indian Gaming Commission (''NIGC'' or ''Commission'').

ACTION: Proposed rules.

SUMMARY: The proposed rules add new sections and a new part to the Commission's regulations in order to ensure that each place, facility or location where class II or class III gaming will occur is located on Indian lands eligible for gaming as required by the Indian Gaming Regulatory Act. The rules are also intended to ensure that gaming facilities are constructed, maintained and operated in a manner that adequately protects the environment and the public health and safety.

DATES: Submit comments on or before December 3, 2007.

ADDRESSES: Comments can be mailed, faxed, or e-mailed. Mail comments to ''Comments on Facility Licensing Standards,'' National Indian Gaming Commission, 1441 L Street, NW., Washington, DC 20005, Attn: Jerrie Moore, Legal Assistant. Comments may be faxed to 202–632–7066 (not a toll-free number). Comments may be sent electronically to *licensing_regulations@nigc.gov*.

FOR FURTHER INFORMATION CONTACT: Penny J. Coleman, Acting General Counsel, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 1988, Congress enacted the Indian Gaming Regulatory Act (''IGRA'' or ''Act''), 25 U.S.C. 2701–21, creating the National Indian Gaming Commission (''NIGC'' or ''Commission'') and developing a comprehensive framework for the regulation of gaming on Indian lands. 25 U.S.C. 2702. The NIGC was granted, among other things, oversight and enforcement authority, including the authority to monitor tribal compliance with the Act, Commission regulations, and tribal gaming ordinances.

First, the IGRA allows gaming on Indian lands pursuant to 25 U.S.C. 2703(4), although it contains a general prohibition against gaming on lands acquired into trust by the United States for the benefit of the tribe after the Act's effective date of October 17, 1988, unless one of several exceptions are met. 25 U.S.C. 2719. The Commission has jurisdiction only over gaming operations on Indian lands and therefore must establish that it has jurisdiction as a prerequisite to its monitoring, enforcement, and oversight duties. 25 U.S.C. 2702(3).

Second, the NIGC needs to obtain information on a tribe's environmental and public health and safety laws to oversee the implementation of approved tribal gaming ordinances. Before opening a gaming operation, a tribe must adopt an ordinance governing gaming activities on its Indian lands. 25 U.S.C. 2710. The Act specifies a number of mandatory provisions to be contained in each tribal gaming ordinance and subjects such ordinances to agency review and the NIGC Chairman's approval. *Id.* Approval by the Chairman is predicated on the inclusion of each of the specified mandatory provisions in the tribal gaming ordinance. *Id.* Among these is a requirement that the ordinance must contain a provision ensuring that ''the construction and maintenance of the gaming operation, and the operation of that gaming is conducted in a manner that adequately protects the environment and the public health and safety.'' 25 U.S.C. 2710(b)(2)(E). Since 1993, when the Commission became operational, the Chairman has required each tribal gaming ordinance submitted for approval to include the express environmental and public health and safety statement set out in 25 U.S.C. 2710(b)(2)(E).

The Commission recognizes that tribal governments, as an incident of inherent tribal sovereignty, have broad autonomy and authority over internal tribal affairs, including, in particular, matters pertaining to tribal lands and the health and welfare of the people and the community. Moreover, the Commission is aware that the principle of tribal self-determination is a cornerstone of federal Indian law and policy and has remained so for more than a quarter century.

The Commission believes that tribes must have some form of basic laws in the following environmental and public health and safety areas: (1) Emergency preparedness, including but not limited to fire suppression, law enforcement and security; (2) food and potable water; (3) construction and maintenance; (4) hazardous materials; and (5) sanitation (both solid waste and wastewater). Accordingly, in 2002, the Commission issued an interpretive rule for environment, public health, and safety. 67 FR 46,109 (Jul. 12, 2002) (''Interpretive Rule'').

The NIGC has conducted many environment and public health and safety inspections since the issuance of the Interpretive Rule and has worked with a consultant to allow the agency to gain expertise in this area. Through this inspection process, the NIGC has identified weaknesses in tribal laws or enforcement thereof and has worked with tribes to cure deficiencies.

The Commission respects the rights of tribes to develop their own laws and be