TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.97	7	1	7	160	1,120[1]
314.70	2	1	2	20	40[2]
Total					1,160

[1]Reporting burden for manufacturers of nonsterile products.
[2]Reporting burden for manufacturers of sterile products.

Because of the estimated increase from the proposed rule to the final rule in the number of respondents for nonsterile products, the number of recordkeepers in the recordkeeping burden of Table 2 has increased by two from the proposed rule. FDA estimated a total of seven recordkeepers in the proposed rule and now estimates a total of nine recordkeepers as a result of new data collected by ERG. The proposed rule estimated 2 hours per record, and FDA's review of that estimate and its experience with the control and validation of microbiological contamination supports this proposed estimate. Therefore, the total number of hours for the recordkeeping burden has increased from 14 hours to 18 hours.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
211.113(b)	9	1	9	2	18
Total					18

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

VIII. Federalism

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

IX. Reference

The following reference is on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eastern Research Group, ''Cost Impact on the Pharmaceutical Industry of Final Sterility Requirements for Inhalation Solution Products,'' 1998.

List of Subjects in 21 CFR Part 200

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 200 is amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360e, 371, 374, 375.

2. Section 200.51 is added to subpart C to read as follows:

§ 200.51 Aqueous-based drug products for oral inhalation.

(a) All aqueous-based drug products for oral inhalation must be manufactured to be sterile.

(b) Manufacturers must also comply with the requirements in § 211.113(b) of this chapter.

Dated: February 1, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–13210 Filed 5–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 123

[Public Notice 3318]

Exports of Commercial Communications Satellite Components, Systems, Parts, Accessories and Associated Technical Data

AGENCY: Bureau of Political-Military Affairs, State.

ACTION: Interim final rule.

SUMMARY: Section 1309(a) of the Foreign Relations Authorization Act for Fiscal Years 2000 and 2001 requires the Department of State to establish a regulatory regime for the export licensing to U.S. allies of commercial satellites, technologies, components, and systems, which shall include expedited approval, as appropriate, while ensuring priority to national security and U.S. commitments under the Missile Technology Control Regime.

Section 1302(a) of the same Act requires the Department to promulgate regulations in order to ensure timely reporting to the Department (within 15

days of shipment or export) of all shipment information concerning items exported pursuant to section 38 of the Arms Export Control Act. The Department will phase-in the reporting requirements for shipment information during the remainder of Calendar Year 2000 through publication of a separate rule change. However, U.S. exporters wishing to take advantage of the special regulatory regime for satellite related licensing to U.S. allies established in this amendment will need to meet the reporting requirements of section 1302(a) in accordance and coincident with the effective date of this amendment or their initial license application submissions. In order to facilitate use of the special regime, the Office of Defense Trade Controls will make available free of charge to U.S. exporters the computer software and guidance for its use that are needed to participate fully.

This interim final rule amends the International Traffic in Arms Regulations (ITAR) by establishing a new regulatory regime for communications satellite related exports to U.S. allies.

EFFECTIVE DATE: July 1, 2000.

FOR FURTHER INFORMATION CONTACT: William Lowell or Terry Davis, Office of Defense Trade Controls, Department of State, Telephone (202) 663–2700 or FAX (202) 261–8264, ATTN: Regulatory Change, Commercial Communications Satellites.

SUPPLEMENTARY INFORMATION: Section 1309(a) of the Foreign Relations Authorization Act for Fiscal Years 2000 and 2001 provides that the Secretary of State shall establish a regulatory regime for licensing the export of commercial satellites, satellite technologies, their components, and systems which shall include expedited approval, as appropriate, of the licensing for export by U.S. companies of such items to NATO allies and major non-NATO allies. Pursuant to § 1309(a) the regime should include expedited processing of requests for export authorizations that are time critical (including information exchange relating to satellite failures or anomalies); are required to submit bids to foreign persons for procurements; are related to re-export of unimproved materials, products, or data; or are required to obtain launch and on-orbit insurance.

Within this legislative framework, the Department of State (Office of Defense Trade Controls) and the Department of Defense (Defense Threat Reduction Agency/Technology Policy) convened in January 2000 a task force of U.S. aerospace industry experts who were members of the State Department's federal advisory committee for defense trade matters, the Defense Trade Advisory Group (DTAG). This DTAG task force met regularly with State and Defense in the period January–April 2000 for the purpose of setting forth a special licensing regime involving U.S. allies that would reflect experience gained since the transfer of commercial communications satellites to the U.S. Munitions List, which became effective March 15, 1999. This task force also drew on the technical and business expertise of other U.S. aerospace industry representatives in discrete product lines (particularly those involved in the supply of components and systems) and held a town hall discussion of the special licensing regime included herein at the April 2–4, 2000 Spring Conference of the Society for International Affairs, a non-profit association comprised of defense firms, held at Laguna Beach, California.

The ITAR amendment herein concerns the special satellite regime involving U.S. allies, provided for by authorizing legislation for exports and re-exports of U.S. Munitions List controlled articles for satellites to, within and among the territories of the member countries of NATO (Belgium, Canada, Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain, Turkey, United Kingdom and the United States) and countries that have been designated pursuant to the Foreign Assistance Act of 1961, as amended, as major non-NATO allies (Australia, New Zealand, Japan, Israel, Egypt, Jordan, Republic of Korea and Argentina). This coverage also includes exports and re-exports of U.S. Munitions List controlled articles for approved satellite projects to be launched from the United States or the territory of a NATO or major non-NATO ally. Importantly, unless otherwise specifically authorized at the time of license approval, this special satellite regime does not apply to any other country in any measure, including but not limited to intermediate consignment occurring during the initial export; temporary re-transfer or re-export; or launch into outer space of USML-controlled articles, whether or not incorporated (*e.g.,* embedded) in a satellite when that activity involves a country that is not a member of NATO or a major non-NATO ally of the United States.

The special satellite regime has three principal features. The first is the ability to use high volume licenses (*e.g.,* known in the trade as ''bulk'' licenses) for exports of specifically designed or modified components, parts, systems, accessories, attachments and certain associated technical data for commercial communications satellites under specified conditions for multiple shipments to any of the NATO or major non-NATO allies.

The second principal feature concerning use of this regime is that all eligible articles for export must be confined to an approved list of foreign aerospace firms located within the territories of U.S. allies for use in an approved list of commercial communications satellite programs of U.S. allies. The lists of foreign aerospace firms and commercial communications satellite programs included within the coverage of this regime will be kept under scrutiny by the U.S. Government and made publicly available on ODTC's Website and by other means. New firms and programs will be added to these lists following scrutiny within the U.S. Government (and approved for inclusion within the regime) in light of proposals from U.S. aerospace firms through export license applications.

Third, when exporting pursuant to the special regime, it is not necessary under specified conditions for U.S. exporters to provide in advance the details of purchase orders or contracts, or non transfer and end use certificates (*e.g.,* form DSP–83) where they may be required. While all of this documentation will continue to be mandatory, and while exporters will continue to be required to ascertain the specific end users and end uses prior to export or re-export, the required documentation will only be required to be furnished to ODTC within 15 days following shipment from the United States (or re-transfer within the approved territory), at which time U.S. exporters will report the appropriate shipping information (discussed further below) and furnish the required documentation.

For sensitive components, such as MTCR-controlled items, the long standing controls of the ITAR, including non-transfer and end use certificates, parts control plans, and the like, will continue to be required. But, in most cases, such documentation may be furnished within 15 days of shipment, as described below. Restrictions may also be imposed on such licenses, however, in view of the specific items proposed for export as appropriate in furtherance of the security and foreign policy of the United States (*e.g.,* to meet missile nonproliferation objectives). Further, for particularly sensitive articles or information, the U.S. Government retains the discretion to require a separate license when

necessary in furtherance of the security and foreign policy of the United States.

The principal articles envisaged for the special regime are: (1) The supply of satellite components, parts, systems, attachments, accessories and associated technical data, including for off-shore procurement; and, (2) technical information needed to respond to bids, to requests for quotations, plant visits, acceptance testing of equipment and the like. Technical data for satellite insurance purposes, including for on-orbit anomalies, involving exports to insurance firms and their brokers and consultants located within the territories of U.S. allies has also been discussed extensively within DTAG and will be the subject of separate, informal guidelines not requiring an amendment to the ITAR.

Exports of complete commercial communications satellites for sale to, or launch by, U.S. allies have been proceeding expeditiously consistent with the Department of State's January 1999 report to Congress concerning implementation of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. Such exports invariably involve contracts of $50 million or more, requiring notification to Congress pursuant to section 36(c) of the Arms Export Control Act before an export license may be issued. As such, these exports do not lend themselves to the special regime provided for herein and no rule change to that effect is being undertaken at this time. As suggested in the referenced report, the Department of State and the interested Committees of Congress have used all appropriate opportunities to ensure that U.S. aerospace companies are able to meet contract deadlines and launch schedules consistent with the security and foreign policy of the United States. The details of communications satellite notifications to Congress that have taken place since March 15, 1999, are available on the Website of the Office of Defense Trade Controls (HYPERLINK http://www.pmdtc.org.).

In carrying out this directive Part 123, Licenses for the Export of Defense Articles is being amended.

This amendment involves a foreign affairs function of the United States and therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found to be a minor rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the States, 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 § 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Order Nos. 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, Part 123—Commercial Communications Satellites Components, Systems, Parts, and Accessories, 13th Floor, Room H1304, SA–1, Washington, D.C. 20520–0113. Such persons must be so registered with the Department's Office of Defense Trade Controls (ODTC) pursuant to the registration requirements of § 38 of the Arms Export Control Act.

List of Subjects in 22 CFR Part 123

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 123, is amended as follows:

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

1. The authority citation for Part 123 is revised to read as follows:

Authority: Secs. 2, 38, and 71, Pub.L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub L. 105–261.

2. Section 123.27 is revised to read as follows:

§ 123.27. Special licensing regime for export to U.S. allies of commercial communications satellite components, systems, parts, accessories, attachments and associated technical data.

(a) U.S. persons engaged in the business of exporting specifically designed or modified components, systems, parts, accessories, attachments, associated equipment and certain associated technical data for commercial communications satellites, and who are so registered with the Office of Defense Trade Controls pursuant to part 122 of this subchapter, may submit license applications for multiple permanent and temporary exports and temporary imports of such articles for expeditious consideration without meeting the documentary requirements of § 123.1(c)(4) and (5) concerning purchase orders, letters of intent, contracts and non-transfer and end use certificates, or the documentary requirements of § 123.9, concerning approval of re-exports or re-transfers, when all of the following requirements are met:

(1) The proposed exports or re-exports concern exclusively one or more countries of the North Atlantic Treaty Organization (Belgium, Canada, Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, Italy, Luxembourg, The Netherlands, Norway, Poland, Portugal, Spain, Turkey, United Kingdom and United States) and/or one or more countries which have been designated in accordance with section 517 of the Foreign Assistance Act of 1961 as a major non-NATO ally (and as defined further in section 644(q) of that Act) for purposes of that Act and the Arms Export Control Act (Argentina, Australia, Egypt, Israel, Japan, Jordan, New Zealand and Republic of Korea).

(2) The proposed exports concern exclusively one or more foreign persons (*e.g.,* companies or governments) located within the territories of the countries identified in paragraph (a)(1) of this section, and one or more commercial communications satellite programs included within a list of such persons and programs approved by the U.S. Government for purposes of this section, as signified in a list of such persons and programs that will be publicly available through the Internet Website of the Office of Defense Trade Controls and by other means.

(3) The articles are not major defense equipment sold under a contract in the amount of $14,000,000 or more or defense articles or defense services sold under a contract in the amount of $50,000,000 or more (for which purpose, as is customary, exporters may not split contracts or purchase orders). Items meeting these statutory thresholds must be submitted on a separate license application to permit the required notification to Congress pursuant to section 36(c) of the Arms Export Control Act.

(4) The articles are not detailed design, development, manufacturing or production data and do not involve the manufacture abroad of significant military equipment.

(5) The U.S. exporter reports complete shipment information to the Office of Defense Trade Controls within 15 days of shipment in accordance with section 1302 of the Foreign Relations Authorization Act for Fiscal Years 2000 and 2001, and at that time meets the documentary requirements of § 123.1(c)(4) and (5), the documentary requirements of § 123.9 in the case of re-exports or re-transfers, and, other documentary requirements that may be imposed as a condition of a license (*e.g.*, parts control plans for MTCR-controlled items). The shipment information reported must include a description of the item and quantity, value, port of exit and end user and country of destination of the item.

(6) At any time in which an item exported pursuant to this section is proposed for re-transfer outside of the approved territory, programs or persons (*e.g.,* such as in the case of an item included in a satellite for launch beyond the approved territory), the detailed requirements of § 123.9 apply with regard to

obtaining the prior written consent of the Office of Defense Trade Controls.

(b) The re-export or re-transfer of the articles authorized for export (including to specified re-export destinations) in accordance with this section do not require the separate prior written approval of the Office of Defense Trade Controls provided all of the requirements in paragraph (a) of this section are met.

(c) The Office of Defense Trade Controls will consider, on a case-by-case basis, requests to include additional foreign companies and satellite programs within the geographic coverage of a license application submitted pursuant to this section from countries not otherwise covered, who are members of the European Space Agency or the European Union. In no case, however, can the provisions of this section apply or be relied upon by U.S. exporters in the case of countries who are subject to the mandatory requirements of section 1514 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, concerning national security controls on satellite export licensing.

(d) Registered U.S. exporters may request at the time of a license application submitted pursuant to this section that additional foreign persons or communications satellite programs be added to the lists referred to in paragraph (a)(2) of this section, which additions, if approved, will be included within the publicly available lists of authorized recipients and programs.

Dated: May 16, 2000.

Eric D. Newsom,

Assistant Secretary, Bureau of Political-Military Affairs, U.S. Department of State.

[FR Doc. 00–13329 Filed 5–25–00; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–147–FOR]

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving an amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to its statutes that would allow the use of money from its post-1977 abandoned mine reclamation fund, under specified circumstances, to replace domestic water supplies disrupted or affected by surface coal mining and reclamation operations. Indiana intends to revise its program in order to provide additional protection to society and the environment from the adverse effects of surface coal mining operations.

EFFECTIVE DATE: May 26, 2000.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone (317) 226–6700. Internet: INFOMAIL@indgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. You can find background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the July 26, 1982 **Federal Register** (47 FR 32107). You can find later actions on the Indiana program at 30 CFR 914.10, 914.15, 914.16, and 914.17.

II. Submission of the Amendment

By letter dated February 25, 2000 (Administrative Record No. IND–1686), the Indiana Department of Natural Resources (department) sent us an amendment to its program under SMCRA and the Federal regulations at 30 CFR 732.17(b). The department sent the amendment at its own initiative. The amendment concerns revisions to the Indiana Surface Coal Mining and Reclamation Act at Indiana Code (IC) 14–34–6–15. The revisions made to IC 14–34–6–15 will allow the department to use money from its post-1977 abandoned mine reclamation fund to replace domestic water supplies disrupted or affected by surface coal mining and reclamation operations.

We announced receipt of the amendment in the March 9, 2000, **Federal Register** (65 FR 12492). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. The public comment period closed on April 10, 2000. Because no one requested a public hearing or meeting, we did not hold one.

III. Director's Findings

Following, under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are our findings concerning the amendment.

IC 14–34–6–15 Abandoned Mine Reclamation Fund

Indiana revised IC 14–34–6–15(b) and (c) to read as follows:

(b) The post-1977 abandoned mine reclamation fund is established. The fund consists of bond forfeiture money collected under section 16 of this chapter and the civil penalties described in IC 14–34–16–9. The fund may be used as follows:

(1) To effect the restoration of land not otherwise eligible for federal funding on which there has been surface mining activity after August 3, 1977.

(2) To replace domestic water supplies disrupted or affected by a surface coal mining and reclamation operation, including the disposal of coal combustion waste (as defined in IC 13–19–3–3), where the surface coal mining and reclamation operation has been completed and is no longer subject to IC 14–34.

The money held for this purpose may not exceed an amount established by the department that is sufficient to enable the director to cover the anticipated cost of restoration.

(c) At least five hundred thousand dollars ($500,000) in the fund is dedicated as collateral for the bond pool under IC 14–34–8 and may not be used for the restoration of land or replacement of water described in subsection (b).

Indiana's post-1977 abandoned mine reclamation fund (fund) consists of both bond forfeiture and civil penalty monies. However, only the monies collected for civil penalties may be used for the purposes specified in IC 14–34–6–15(b). Under IC 14–34–6–16(f), the bond forfeiture monies are to be used solely for the purpose of reclaiming the forfeiture sites to which the bonds apply. Under IC 14–34–6–16(d), any excess forfeited bond money must be returned to the person from whom the amount was received. Under IC 14–34–6–15(b)(1), the civil penalty money in the fund may be used to restore land affected by surface mining activity after August 3, 1977, if the land is not eligible for Federal funding. Under the new provision at IC 14–34–6–15(b)(2), the civil penalty money in the fund may be used to replace domestic water supplies disrupted or affected by a surface coal mining and reclamation operation, if the operation is completed and is no longer subject to the requirements of the Indiana program under IC 14–34. Indiana revised its exception provision at IC 14–34–6–15(c) to clarify that the $500,000 that is dedicated as collateral for the Indiana bond pool may not be