3. MOSO Company

4. The Scientific Research and Design Institute of Power Technology (aka NIKIET, Research and Development Institute of Power Engineering (RDIPE), and ENTEK).

The Department of State made its determination with regard to, and imposed nonproliferation measures against, Europalace 2000, Grafit, and MOSO Company on July 30, 1998 (63 FR 42089). BIS imposed conforming license requirements on these three entities under the EAR on July 29, 1998 (63 FR 40363). The Department of State made its determination with regard to, and imposed nonproliferation measures against, the Scientific Research and Design Institute of Power Technology on January 8, 1999 (64 FR 2935), and BIS imposed license requirements on this entity under the EAR on March 26, 1999 (64 FR 14605).

On March 23, 2004, the Department of State determined that it is in the foreign policy and national security interests of the United States to remove nonproliferation measures imposed on these four Russian entities (69 FR 17262). In conformance with this determination, this final rule removes the license requirements under section 744.10 for exports and reexports to these entities, and removes these entities from the Entity List.

The removal of these entities from the Entity List eliminates the license requirements under section 744.10 of the EAR for exports and reexports to these entities. However, license requirements for exports and reexports set forth in part 744 still apply to these entities when the exporter or reexporter knows that the item will be used in a prohibited activity. BIS strongly urges the use of Supplement No. 3 to part 732 of the EAR, ''BIS's 'Know Your Customer' Guidance and Red Flags'' when exporting or reexporting.

Although the Export Administration Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (66 FR 44025, August 22, 2001), extended by the Notice of August 6, 2004, 69 FR 48763 (August 10, 2004), continues the EAR in effect under the International Emergency Economic Powers Act.

**Rulemaking Requirements**

1. This final rule has been determined to be not significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves a collection of information subject to the PRA. This collection has been approved by OMB under control number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 58 minutes for a manual or electronic submission. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to David Rostker, Office of Management and Budget (OMB), by e-mail to *David_Rostker@omb.eop.gov,* or by fax to (202)395–7285; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6883, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Please refer to the **ADDRESSES** section cited above for comment submission.

**List of Subjects in 15 CFR Part 744**

Exports, Foreign trade, Reporting and recordkeeping requirements.

■ Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

## PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of November 9, 2001, 66 FR 56965, 3 CFR, 2001 Comp., p. 917; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

■ 2. Supplement No. 4 to part 744 is amended by removing entries for the entities ''Europalace 2000, Moscow,'' ''Grafit (a.k.a. State Scientific Research Institute of Graphite or NIIGRAFIT), 2 Ulitsa Elektrodnaya, 111524, Moscow,'' ''MOSO Company, Moscow,'' and ''The Scientific Research and Design Institute of Power Technology (a.k.a. NIKIET, Research and Development Institute of Power Engineering (RDIPE), and ENTEK) (including at 101000, P.O. Box 788, Moscow, Russia)'' under the country of ''Russia''.

Dated: November 8, 2004.

**Peter Lichtenbaum,**

*Assistant Secretary for Export Administration.*

[FR Doc. 04–25308 Filed 11–12–04; 8:45 am]

**BILLING CODE 3510–33–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 180

**[Docket No. 2004F–0066]**

## Food Additives Permitted in Food on an Interim Basis or in Contact With Food Pending Additional Study; Mannitol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, or maltose by the action of the microorganism *Lactobacillus intermedius* (*fermentum*). This action is in response to a petition filed by zuChem, Inc.

**DATES:** This rule is effective November 15, 2004. Submit written or electronic objections and requests for a hearing by December 15, 2004.

**ADDRESSES:** You may submit written objections and requests for a hearing,

identified by Docket No. 2004F–0066, by any of the following methods:

- 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.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004F–0066 in the subject line of your e-mail message.
- 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.

*Instructions*: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading 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:** Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In a notice published in the **Federal Register** of February 19, 2004 (69 FR 7759), FDA announced that a food additive petition (FAP 4A4754) had been filed by zuChem, Inc., c/o Hyman, Phelps and McNamara, P.C., 700 13th Street NW., Washington, DC 20005. The petition proposed to amend the food additive regulations in § 180.25 *Mannitol* (21 CFR 180.25) to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, and maltose by the action of the microorganism *L. intermedius* (*fermentum*).

In 1973, the agency proposed to affirm mannitol as generally recognized as safe (GRAS) based on the findings by the Select Committee on GRAS Substances from the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (38 FR 20046, July 26, 1973). In response to the proposal, the agency received comments, including information raising questions about the safety of mannitol. Rather than affirm the GRAS status of mannitol, the agency instead decided to establish an interim food additive regulation for mannitol, pending additional study of the ingredient (39 FR 34178, September 23, 1974) and based on the conclusion that there would be no increased risk to the public health to continue existing uses and levels of use of mannitol while additional studies were carried out. The regulation was subsequently amended (61 FR 7990, March 1, 1996) to permit the manufacture of mannitol by fermentation of sugars or sugar alcohols by the action of the yeast *Zygosaccharomyces rouxii*.

The proposed fermentation organism, *L. fermentum*, is currently used in various food applications. For example, strains of *L. fermentum* are used in sourdough bread and pressed curd cheeses, and FDA has affirmed as GRAS a urease preparation from *L. fermentum* for use in the manufacture of wine. The petitioner has submitted data in support of the microbiological safety of mannitol produced by this bacterium. In addition, the petitioner has provided detailed information on the process used to produce mannitol by this fermentation method, including information on the purification steps that are used. FDA concludes, having considered the evidence concerning the production organism and the purification procedures, that *L. intermedius* (*fermentum*) will not be present in the final product and can be safely used in the fermentation of fructose and other sugars to produce mannitol provided that the purity of the culture is maintained, and that a nonpathogenic, nontoxicogenic strain of *L. intermedius* (*fermentum*) is used (Ref. 1).

## II. Conclusion

The current interim regulation for mannitol specifies manufacturing procedures that do not include the proposed fermentation process. FDA has reviewed data and information in the petition on the chemical equivalence of mannitol produced using *L. intermedius* (*fermentum*) and mannitol produced by the currently-regulated methods. Based on its review, the agency concludes that mannitol manufactured by fermentation of sugars by the action of *L. intermedius* (*fermentum*) is equivalent to mannitol produced by the currently-regulated methods as described in § 180.25. In addition, mannitol manufactured by the proposed fermentation process will have the same intended technical effect and uses as mannitol produced by the currently-regulated methods. Consequently, there will be no change in exposure to mannitol (Refs. 2 and 3). Therefore, FDA concludes that § 180.25 should be amended as set forth in this document.

## III. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

## IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 4A4754. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

## V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event

that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

### VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA memorandum from P. C. DeLeo, Division of Petition Review, to C. Johnston, Division of Petition Review, April 21, 2004.

2. FDA memorandum from D. E. Folmer, Division of Petition Review, to C. Johnston, Division of Petition Review, April 20, 2004.

3. FDA memorandum from D. E. Folmer, Division of Petition Review, to C. Johnston, Division of Petition Review, July 29, 2004.

### List of Subjects in 21 CFR Part 180

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 180 is amended as follows:

## PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

■ 1. The authority citation for 21 CFR part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

■ 2. Section 180.25 is amended by adding paragraph (a)(3) to read as follows:

### § 180.25 Mannitol.

(a) * * *

(3) A pure culture fermentation of sugars such as fructose, glucose, or maltose using the nonpathogenic, nontoxicogenic bacterium *Lactobacillus intermedius* (*fermentum*).

* * * * *

Dated: October 27, 2004.

**Leslye M. Fraser,**

*Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

[FR Doc. 04–25243 Filed 11–12–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF JUSTICE

## 28 CFR Part 0

**[AG Order No. 2738–2004]**

## Delegations of Authority; Federal Bureau of Investigation

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** Recent consultations between criminal law enforcement investigative agencies and the Department of Justice have suggested the need to simplify and clarify the delegations of authority to the Federal Bureau of Investigation to investigate any criminal violations of law in certain foreign counterintelligence areas. This final rule changes the language of the delegations of authority to eliminate confusion about the scope of the delegation.

**EFFECTIVE DATE:** November 15, 2004.

**FOR FURTHER INFORMATION CONTACT:** Bruce C. Swartz, Deputy Assistant Attorney General, Criminal Division, United States Department of Justice, Washington, DC 20530 (202) 514–2333 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Attorney General has authority to investigate any violation of the criminal laws of the United States. 28 U.S.C. 533. As a general proposition, the Attorney General has delegated general investigative authority to the Federal Bureau of Investigation. 28 CFR 0.85(a). Recent consultations among investigative agencies have indicated that confusion has been created by the use of limiting language in the formal delegations of authority within the Department. The limitation of the Federal Bureau of Investigation's authority to the extent that investigative authority is assigned elsewhere was not intended as other than an internal management tool. The Department has determined that the limitation should be stated more clearly and applicable only when statute or other authority, such as an Executive Order or Attorney General delegation, assigns investigative authority exclusively to another agency or component. Accordingly, this final rule amends the language in 28 CFR part 0.

### Administrative Procedure Act

This rule relates to matters of agency management and personnel and, therefore, is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. *See* 5 U.S.C. 553(a)(2) and (d). The rule only alters an internal delegation to the Federal Bureau of Investigation.

### Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. Further, a Regulatory Flexibility Analysis is not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter.

### Executive Order 12866

This rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation. This rule is limited to agency organization, management and personnel matters as described by Executive Order 12866, § 3(d)(3) and, therefore, is not a ''regulation'' or ''rule'' as defined by that Executive Order.

### Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

### Executive Order 13132

This rule 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 13132, Federalism, the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

### 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 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

### Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 804. This rule will not result in an