Rules and Regulations

Federal Register
Vol. 75, No. 210
Monday, November 1, 2010

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 101006492–0494–02]

RIN 0694–AF02

Amendment to Existing Validated End-User Authorization in the People's Republic of China: Semiconductor Manufacturing International Corporation

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this action, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to remove one facility from the list of Semiconductor Manufacturing International Corporation (SMIC) facilities that are authorized to receive certain items in the People's Republic of China (PRC) under SMIC's validated end-user (VEU) authorization. Specifically, BIS removes Cension Semiconductor Manufacturing Corporation (Cension) from SMIC's list of approved VEU facilities in the PRC due to a material change at SMIC. This amendment is not the result of prohibited activities by Cension or by SMIC, nor does it establish any new license requirements or more restrictive licensing policies for exports, reexports or transfers (in-country) of items to the facility identified in this rule; license requirements set forth in the EAR continue to apply to this facility.

DATES: This rule is effective November 1, 2010. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

ADDRESSES: You may submit comments, identified by RIN 0694–AF02 by any of the following methods:

E-mail: publiccomments@bis.doc.gov. Include "RIN 0694–AF02" in the subject line of the message.

Fax: (202) 482–3355. Please alert the Regulatory Policy Division, by calling (202) 482–2440, if you are faxing comments.

Mail or Hand Delivery/Courier: Sheila Quarterman, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th Street & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, Attn: RIN 0694–AF02.

Send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), by e-mail to *Jasmeet_K._Seehra@omb.eop.gov* or by fax to (202) 395–7285. Comments on this collection of information should be submitted separately from comments on the final rule (*i.e.,* RIN 0694–AF02)—all comments on the latter should be submitted by one of the three methods outlined above.

FOR FURTHER INFORMATION CONTACT: Karen Nies-Vogel, Chairman, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue, NW., Washington, DC 20230; by telephone (202) 482–3811, or by e-mail to *kniesv@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Authorization Validated End-User

Consistent with U.S. Government policy to facilitate trade for civilian end-users in the PRC, on June 19, 2007 BIS amended the EAR in a final rule (72 FR 33646) to create a new authorization to allow "validated end-users" (VEUs) located in eligible destinations to receive certain items through export, reexport or transfer (in-country) under a general authorization rather than requiring a license. 15 CFR 748.15. Companies listed as VEUs may obtain eligible items that are on the Commerce Control List, set forth in Supplement No. 1 to part 774 of the EAR, without having to wait for their suppliers to obtain export licenses from BIS. Eligible items may include commodities, software and technology, except for those items that are controlled for missile technology or crime control reasons.

Authorization VEU is a mechanism to facilitate increased high-technology exports to companies in eligible destinations that have a verifiable record of civilian uses for such items. The validated end-users listed in Supplement No. 7 to Part 748 of the EAR were reviewed and approved by the U.S. Government in accordance with the provisions of Section 748.15 and Supplement Nos. 8 and 9 to Part 748 of the EAR. In addition to U.S. exporters, Authorization VEU may be used by foreign reexporters and persons transferring in-country, and does not have an expiration date. Currently, VEUs are located in the PRC and India.

Removal of Cension Semiconductor Manufacturing Corporation (Cension) From the List of Validated End-User Semiconductor Manufacturing International Corporation's (SMIC's) Approved Facilities in the PRC

In a rule published in the **Federal Register** on October 19, 2007 (72 FR 59231), BIS designated SMIC as a VEU, thus authorizing certain specific exports, reexports and transfers (in-country) to the five listed facilities of the company, including Cension. Due to a material change at the Cension facility of SMIC, and consistent with section 748.15 of the EAR, BIS now amends Supplement No. 7 to Part 748 of the EAR to remove the Cension facility from that list of SMIC's approved VEU facilities. This change leaves four SMIC facilities that are approved to receive eligible items under SMIC's VEU authorization. Cension's address (*i.e.,* 3/F, 8–1 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731) will also be removed from the list of SMIC's authorized VEU facilities. As a result of this rule, the Cension facility will no longer be authorized to receive items through Authorization VEU. Thus, parties seeking to export, reexport or transfer (in-country) items under the EAR to the Cension facility may now have to obtain a license to do so, depending on the item at issue.

This amendment is not the result of prohibited activities by Cension or SMIC. SMIC remains a qualified participant in the VEU program and exports, reexports and transfers (in-country) of the items controlled under the export control classification numbers listed in SMIC's entry in Supplement No. 7 to Part 748 of the

EAR to the SMIC facilities listed in the same part may continue to be made under Authorization VEU. Nor does this action establish any new license requirements, or more restrictive licensing policies, for exports, reexports or transfers (in-country) of items to the Cension facility. Rather, the license requirements set forth in the EAR continue to apply to this facility.

Note that this amendment applies only to transactions under Authorization VEU involving SMIC's Cension facility. All conditions and restrictions that applied to transactions that were undertaken pursuant to Authorization VEU prior to the effective date of this amendment, and that involve the Cension facility, continue to apply to those transactions. These restrictions and conditions include any that were imposed on this facility in connection with its eligibility for Authorization VEU, as established by BIS in its communications authorizing the Cension facility's participation in the VEU program.

Saving Clause

Shipments of items removed from eligibility for export, reexport or transfer (in-country) under Authorization VEU (i.e., under the designator VEU) as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on November 1, 2010, pursuant to actual orders for export, reexport or transfer (in-country) to an eligible destination, may proceed to that destination under the previously applicable Authorization so long as they are exported, reexported or transferred (in-country) before November 16, 2010. Any such items not actually exported, reexported or transferred (in-country) before midnight, on November 16, 2010, require an individual license or other applicable authorization under the EAR.

Since August 21, 2001, the Export Administration Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), as extended most recently by the Notice of August 12, 2010 (75 FR 50681) (August 16, 2010), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. This final rule has been determined to be not significant for the purposes of Executive Order 12866.

2. This rule involves information collections previously approved by OMB under control number 0694–0088, "Multi-Purpose Application" (Form BIS 748). This collection has a burden hour estimate of 58 minutes for the preparation and submission of the form, and an estimated burden of 30 minutes per submission for recordkeeping, reporting and review requirements in connection with the Authorization VEU program. Although this rule may result in a slight increase in license applications, this rule is not expected to impact the information collection request previously approved by OMB under control number 0694–0088.

Notwithstanding any other provisions of law, no person is required to respond to nor 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 OMB Control Number.

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

4. There is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act (APA) requiring prior notice and the opportunity for public comment because, specific to this rule, they are unnecessary, impracticable and contrary to the public interest.

In determining whether to grant or revoke validated end-user designations, a committee of U.S. Government agencies evaluates a variety of information, the nature and terms of which are set forth in 15 CFR part 748, Supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2). The information, commitments and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313, July 2, 2006 and 72 FR 33646, June 19, 2007). Thus, authorization of a VEU is similar to granting a license: To receive Authorization VEU, an application must be submitted on behalf of an entity; the entity must be found to meet certain previously identified criteria; and the application must be approved. Because the authorization granted by BIS pursuant to 15 CFR § 748.15 is similar to that granted to exporters for individual licenses, which do not undergo public review when they are approved, denied, revoked, or amended, allowing public review and comments to this rule is unnecessary.

The procedure for revocation of a facility from the Authorized VEU list is similar to the license revocation procedure, and because this rule involves revocation, public comment on it is unnecessary. During the revocation procedure, the U.S. Government analyzes confidential business information according to set criteria to determine whether a given authorized VEU entity remains eligible for VEU status. Revocation may, as in this case, be the result of a material change in circumstance at the authorized facility. Examples of such a material change include changes in the operational status of a VEU facility or changes in the end-use of the products produced at the facility. Such changes may result in a VEU or a VEU facility no longer meeting the eligibility criteria for Authorization VEU, and thus may lead the U.S. Government to modify or revoke VEU authorization. Facilities that undergo material changes that result in their no longer meeting the criteria to be eligible VEUs must, according to the VEU program, have their VEU status revoked. Here, the Cension facility is no longer eligible to be an Authorized VEU, and so, by the terms of the EAR and the VEU program, the facility's VEU status must be revoked; thus public comments on whether to revoke this status are unnecessary.

Additionally, allowing for prior public notice and comment on this rule may be impracticable and contrary to the public interest. The EAR advance U.S. national security, foreign policy, and economic objectives by ensuring an effective export control system. In accordance with the pre-set criteria, the U.S. Government reviews each VEU and its facilities to ensure that exports, reexports and transfers (in-country) of specified items to these entities are consistent with such objectives. Accordingly, VEUs and their facilities may receive through export, reexport or transfer (in-country) items that would otherwise require a license and transaction-specific review, in part due to national security concerns. However, the listed facility here is no longer eligible to be an Authorized VEU facility, and in order to protect national security, the restrictions of the EAR must be in place as soon as possible. Allowing public comments to this rule would hinder the ability of BIS to enforce the EAR's restrictions on exports without a license to the listed facility, and therefore public comment on this rule is both impracticable, because allowing such comment would prevent BIS from undertaking its

statutory duties, and contrary to the public's national security interests.

In addition, BIS finds good cause to waive the requirement of 5 U.S.C. 553(d)(3) to delay the effectiveness of this regulation, because such a delay is contrary to the public's interest. When the U.S. Government has been notified of or has identified a material change in circumstances that warrants revocation or modification of VEU status for an end-user or a facility of an end-user, there is a need to quickly alert the public that the facility is no longer authorized as a recipient of items under Authorization VEU. Delaying this action's effectiveness could result in items that otherwise require licenses being exported, reexported or transferred (in-country), license-free, to an ineligible facility. Accordingly, it would be contrary to the public interest to delay this rule's effectiveness.

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 and no regulatory flexibility analysis has been prepared.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

■ Accordingly, part 748 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010 (75 FR 50681) (August 16, 2010).

■ 2. Supplement No. 7 to part 748 is amended by removing "Cension Semiconductor Manufacturing Corporation" and its address "(3/F, 8–1 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731)" from the list of "Eligible Destinations" for "Validated End-User" "Semiconductor Manufacturing International Corporation" in "China (People's Republic of)".

Dated: October 26, 2010.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2010–27517 Filed 10–29–10; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2010–N–0002]

Oral Dosage Form New Animal Drugs; Domperidone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the original approval of a new animal drug application (NADA) filed by Dechra, Ltd. The NADA provides for the veterinary prescription use of domperidone oral gel for prevention of fescue toxicosis in periparturient mares.

DATES: This rule is effective November 1, 2010.

FOR FURTHER INFORMATION CONTACT: Amy L. Omer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8336, e-mail: *amy.omer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, filed NADA 141–314 that provides for veterinary prescription use of EQUIDONE (domperidone) Gel for prevention of fescue toxicosis in periparturient mares. The NADA is approved as of September 9, 2010, and the regulations in 21 CFR part 520 are amended by adding § 520.766 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.766 to read as follows:

§ 520.766 Domperidone.

(a) *Specifications.* Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) *Indications for use.* For prevention of fescue toxicosis in periparturient mares.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 27, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–27524 Filed 10–29–10; 8:45 am]

BILLING CODE 4160–01–P