

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 744**

[Docket No. 210303–0036]

RIN 0694–A142

Addition of Entities to the Entity List**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to further implement U.S. sanctions on selected Burmese government ministries and related enterprises. Specifically, BIS amends the EAR by adding four entities to the Entity List under the destination of Burma. These four entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. The actions in this rule support the United States Government's efforts to promote a return to democracy in Burma following the February 1, 2021 Burmese military coup. They also reflect the United States Government's goal of supporting the people of Burma by preventing Burma's military and security services from obtaining items subject to the EAR.

DATES: This rule is effective March 8, 2021.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Fax: (202) 482–3911, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:**Entity List**

The Entity List (15 CFR, subchapter C, part 744, Supplement No. 4) identifies entities reasonably believed to be involved in, or to pose a significant risk of being or becoming involved in, activities contrary to the national security or foreign policy interests of the United States. The Export Administration Regulations (EAR) (15 CFR parts 730–774) impose additional license requirements on, and limit the availability of most license exceptions for exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the “License review policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant

Federal Register document adding entities to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote. The Departments represented on the ERC have approved these changes to the Entity List.

Additions to the Entity List Made in Response to the February 1, 2021 Military Coup in Burma

BIS is making additions to the Entity List as part of a broader U.S. Government response to the February 1, 2021 coup by the military in Burma, which overthrew Burma's democratically-elected government, and the military's subsequent arrest and detention of government leaders, human rights defenders, and journalists. On February 10, 2021, President Biden signed Executive Order (E.O.) 14014, “Blocking Property With Respect to the Situation in Burma” (E.O. 14104) in which he declared a national emergency to address the threat posed to the United States by the situation in, and in relation to, Burma following the coup. *See* 86 FR 9429 (Feb. 12, 2021).

Since February 10, 2021, BIS has taken action under the EAR to strengthen export controls on Burma and address the foreign policy and national security concerns that formed the basis for the issuance of E.O. 14104. On February 18, 2021, BIS published a rule in the **Federal Register** adopting a more restrictive review policy of a presumption of denial for license applications involving items subject to the EAR that require a license for export and reexport and that are destined for Burma's Ministry of Defence, Ministry of Home Affairs, armed forces, or security services. The February 18, 2021 rule also suspended the availability in part or in full of four license exceptions in part 740 of the EAR for items destined for Burma. *See* 86 FR 10011 (Feb. 18, 2021). As part of an additional final rule, BIS imposed additional restrictions on Burma, including by removing the country from Country Group B, and placing it in the more restrictive Country Group D:1, and by

adding it to the list of countries subject to defined ‘military end use’ and ‘military end user’ restrictions. *See* supp. no. 1 to part 740 and §§ 742.4 and 744.21 of the EAR.

In this rule, BIS is taking additional steps in response to the situation in Burma. BIS is adding four entities, including specifically identified aliases, to the Entity List under the destination of Burma: The Ministry of Defence, the Ministry of Home Affairs, Myanmar Economic Corporation, and Myanmar Economic Holdings Limited. The actions in this rule support the United States Government's efforts to promote a return to democracy in Burma. In particular, this rule enhances the U.S. Government's efforts to ensure that items subject to the EAR are not available to Burma's Ministry of Defence and the Ministry of Home Affairs, the entities responsible for the coup, or the two commercial entities owned and operated by the Ministry of Defence, Myanmar Economic Corporation and Myanmar Economic Holdings Limited, which provide revenue for the Ministry of Defence.

The departments represented on the ERC reviewed and applied § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these four entities to the Entity List. Under paragraph (b), persons for whom there is reasonable cause to believe, based on specific and articulable facts, that they have been involved, are involved, or pose a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States, along with those acting on behalf of such persons, may be added to the Entity List. Paragraphs (b)(1) through (5) of § 744.11 provide an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States. For each of the four entities identified below, the ERC made the requisite determination based on the standard set forth in § 744.11(b). The four entities added to the Entity List in this rule are involved in activities that are contrary to the national security and foreign policy of the United States by being involved in, or supporting, the military coup in Burma.

For the four entities added to the Entity List in this final rule, BIS imposes a license requirement for all items subject to the EAR and a license review policy of presumption of denial. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. The acronym “a.k.a.” (also known

as) is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters, and transferors in identifying entities on the Entity List.

For the reasons described above, this final rule adds the following four entities to the Entity List.

Burma

- Ministry of Defence;
 - Ministry of Home Affairs;
 - Myanmar Economic Corporation;
- and
- Myanmar Economic Holdings Limited.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on March 8, 2021, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, President Donald J. Trump signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852) that provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

Notwithstanding any other provision of law, no person is required to respond to or 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 regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule.

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

Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

Because a notice of proposed rulemaking and an opportunity for

public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

- 1. The authority citation for part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; 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. 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 September 18, 2020, 85 FR 59641 (September 22, 2020); Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

- 2. Supplement No. 4 to part 744 is amended under Burma by adding in alphabetical order entries for “Ministry of Defence,” “Ministry of Home Affairs,” “Myanmar Economic Corporation,” and “Myanmar Economic Holdings Limited” to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register Citation
BURMA.				
	Ministry of Defence, a.k.a., the following two aliases: —Ministry of Defense; and —MoD. Building 24, Nay Pyi Taw, Burma.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	86 FR [INSERT FR PAGE NUMBER], 3/8/2021.
	Ministry of Home Affairs, a.k.a., the following one alias: —MOHA. Building 10, Nay Pyi Taw, Burma.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER], 3/8/2021.

Country	Entity	License requirement	License review policy	Federal Register Citation
	Myanmar Economic Corporation, a.k.a., the following one alias: —MEC. Corner of Ahlone Road and Strand Road, Ahlone Township, Yangon, Myanmar.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER], 3/8/2021.
	Myanmar Economic Holdings Limited, a.k.a., the following eight aliases: —MEHL; —Myanma Economic Holdings Limited; —Myanma Economic Holdings Public Company Limited; —Myanmar Business Holdings Public Company Limited; —Myanmar Economic Holdings Public Company Limited; —UMEH; —Union of Myanmar Economic Holdings Company Limited; <i>and</i> —Union of Myanmar Economic Holdings Limited. 189–191 Maha Bandoola Road, Botahtaung Township, Yangon, Burma.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER], 3/8/2021.
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Matthew S. Borman,
Deputy Assistant Secretary for Export Administration.
[FR Doc. 2021–04794 Filed 3–4–21; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 526, 529, 556, and 558

[Docket No. FDA–2020–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to

reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during April, May, and June 2020. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective March 8, 2021.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2020, as listed in table 1.

In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (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, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING APRIL, MAY, AND JUNE 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 2, 2020	141–527	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	BAYTRIL 100–CA1 (enrofloxacin) Injectable Solution.	Cattle	Conditional approval for the treatment of clinical anaplasmosis in certain classes of cattle.	FOI Summary.
April 10, 2020 ...	141–533	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	ASERVO EQUIHALER (ciclesonide inhalation spray).	Horses	Original approval for the management of clinical signs associated with severe equine asthma in horses.	FOI Summary.