

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

In the Matter of:)
)
Maine Biological Laboratories, Inc.)
P.O. Box 255)
Waterville, ME 04901)
)
and)
)
China Road)
Winslow, ME 04901)
)

Respondent)

ORDER RELATING TO MAINE BIOLOGICAL LABORATORIES

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”) having notified Maine Biological Laboratories, Inc. (“MBL”) of its intention to initiate an administrative proceeding against MBL pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2005)) (“Regulations”),¹ and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),² by issuing a proposed charging letter to MBL that alleged that MBL committed 12 violations of the Regulations. Specifically, the charges are:

¹ The charged violations occurred from 2001 through 2002. The Regulations governing the violations at issue are found in the 2001- 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2001-2002)). The 2005 Regulations establish the procedures that apply to this matter.

² Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended most recently by the Notice of August 2, 2005, (70 *Fed. Reg.* 45273 (August 5, 2005)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701- 1706 (2000)).

1. *Four Violations of 15 C.F.R. § 764.2(a) - Exporting Avian Vaccines to Syria without the Required Licenses:* On four occasions during the period of in or about January 2001 through in or about February 2002, MBL engaged in conduct prohibited by the Regulations by exporting avian vaccines containing the Newcastle disease virus (“vaccines”), items subject to the Regulations and classified under export control classification number (“ECCN”) 1C991, from the United States to Syria without Department of Commerce licenses as required by Section 742.9 of the Regulations.
2. *Four Violations of 15 C.F.R. § 764.2(e) - Selling Avian Vaccines with Knowledge that a Violation of the Regulations Would Occur:* On four occasions, during the period of in or about January 2001 through in or about February 2002, MBL sold or transferred vaccines, items subject to the Regulations and classified under ECCN 1C991, from the United States to an end-user in Syria with knowledge that violations of the Regulations would occur. MBL knew that a Department of Commerce license was required to export the vaccines from the United States to Syria and MBL sold or transferred the vaccines knowing that they would be exported without the required licenses.
3. *Three Violations of 15 C.F.R. § 764.2(g)- False Statements as to Authority to Export on Shipper’s Export Declarations:* On three occasions during the period of in or about March 2001 through in or about February 2002, MBL made false statements to the U.S. Government by filing or causing to be filed Shipper’s Export Declarations (“SED”) with the U.S. Government that stated that the vaccines being exported qualified for export from the United States to Syria as NLR (“No License

Required”). These statements were false because, as described above, the exports required a license from the Department of Commerce.

4. *One Violation of 15 C.F.R. § 764.2(a)-Failing to File a Shipper's Export*

Declaration for an Export to Syria: On or about January 10, 2001, MBL exported or caused the export of a vaccine, an item classified under ECCN 1C991 of the Regulations, from the United States to Syria without filing an SED. Pursuant to Section 758.1 of the Regulations as then in effect, one “must file an SED...with the United States Government for items subject to the EAR [Export Administration Regulations]...that are destined for Syria ...regardless of value...”

WHEREAS, BIS and MBL have entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and

WHEREAS, I have approved of the terms of such Settlement Agreement;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$100,000 is assessed against MBL, of which \$20,000 shall be paid to the U.S. Department of Commerce not later than December 1, 2005; \$20,000 shall be paid to the U.S. Department of Commerce not later than February 1, 2006; \$20,000 shall be paid to the U.S. Department of Commerce not later than June 1, 2006; \$20,000 shall be paid to the U.S. Department of Commerce not later than September 1, 2006; and \$20,000 shall be paid to the U.S. Department of Commerce not later than December 1, 2006. Payment shall be made in the manner specified in the attached instructions. The timely payment of this penalty is guaranteed by Lohmann Animal Health International (LAHI), a company related to MBL. LAHI and MBL are jointly and severally liable for timely payment of the fine.

SECOND, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C.

§§ 3701-3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein, MBL and LAHI will be assessed, in addition to the full amount of the civil penalty and interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

THIRD, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to MBL. Accordingly, if MBL or LAHI should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of MBL's export privileges for a period of one year from the date of entry of this Order.

FOURTH, for a period of five years from the date of entry of the Order, Maine Biological Laboratories, Inc., P.O. Box 255 Waterville, ME 04901 and China Road, Winslow, ME 04901, its successors or assigns, and when acting for or on behalf of MBL, its officers, representatives, agents, or employees ("Denied Person") may not participate, directly or indirectly, in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

- A. Applying for, obtaining, or using any license, License Exception, or export control document;
- B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

- C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

FIFTH, that no person may, directly or indirectly, do any of the following:

- A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;
- B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;
- C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;
- D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or
- E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

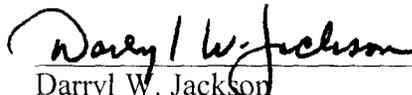
SIXTH, that, to prevent evasion of this Order, BIS, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, may make any person, firm, corporation, or business organization related to MBL by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services subject to the provisions of this Order.

SEVENTH, that this Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

EIGHTH, that, as authorized by Section 766.18 (c) of the Regulations, the denial period set forth above shall be suspended in its entirety for 18 months from the date of this Order, and shall thereafter be waived, provided that during the period of suspension, MBL has committed no violation of the Act or any regulation, order or license issued thereunder.

NINTH, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

This Order, which constitutes the final agency action in this matter, is effective immediately.



Darryl W. Jackson
Assistant Secretary of Commerce
for Export Enforcement

Entered this 7th day of November 2005.

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

In the Matter of:)
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Maine Biological Laboratories, Inc.)
P.O. Box 255)
Waterville, ME 04901)
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and)
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China Road)
Winslow, ME 04901)
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Respondent)

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made by and between Maine Biological Laboratories, Inc. (“MBL”), and the Bureau of Industry and Security, U.S. Department of Commerce (“BIS”) (collectively referred to as “Parties”), pursuant to Section 766.18(a) of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2005)) (“Regulations”)¹, issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”)²,

¹The charged violations occurred from 2001 through 2002. The Regulations governing the violations at issue are found in the 2001 - 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2001-2002)). The 2005 Regulations establish the procedures that apply to this matter.

² Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended most recently by the Notice of August 2, 2005, (70 Fed. Reg. 45273 (August 5, 2005)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701- 1706 (2000)).

WHEREAS, BIS has notified MBL of its intention to initiate an administrative proceeding against MBL, pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to MBL that alleged that MBL committed 12 violations of the Regulations, specifically:

1. *Four Violations of 15 C.F.R. § 764.2(a) - Exporting Avian Vaccines to Syria without the Required Licenses:* On four occasions during the period of in or about January 2001 through in or about February 2002, MBL engaged in conduct prohibited by the Regulations by exporting avian vaccines containing the Newcastle disease virus (“vaccines”), items subject to the Regulations and classified under export control classification number (“ECCN”) 1C991, from the United States to Syria without Department of Commerce licenses as required by Section 742.9 of the Regulations.
2. *Four Violations of 15 C.F.R. § 764.2(e) - Selling Avian Vaccines with Knowledge that a Violation of the Regulations Would Occur:* On four occasions, during the period of in or about January 2001 through in or about February 2002, MBL sold or transferred vaccines, items subject to the Regulations and classified under ECCN 1C991, from the United States to an end-user in Syria with knowledge that violations of the Regulations would occur. MBL knew that a Department of Commerce license was required to export the vaccines from the United States to Syria and MBL sold or transferred the vaccines knowing that they would be exported without the required licenses.

3. *Three Violations of 15 C.F.R. § 764.2(g)- False Statements as to Authority to Export on Shipper's Export Declarations:* On three occasions during the period of in or about March 2001 through in or about February 2002, MBL made false statements to the U.S. Government by filing or causing to be filed Shipper's Export Declarations ("SED") with the U.S. Government that stated that the vaccines being exported qualified for export from the United States to Syria as NLR ("No License Required"). These statements were false because, as described above, the exports required a license from the Department of Commerce.
4. *One Violation of 15 C.F.R. § 764.2(a)-Failing to File a Shipper's Export Declaration for an Export to Syria:* On or about January 10, 2001, MBL exported or caused the export of a vaccine, an item classified under ECCN 1C991 of the Regulations, from the United States to Syria without filing an SED. Pursuant to Section 758.1 of the Regulations as then in effect, one "must file an SED...with the United States Government for items subject to the EAR [Export Administration Regulations]...that are destined for Syria ...regardless of value...."

WHEREAS, MBL has reviewed the proposed charging letter and is aware of the allegations made against it and the administrative sanctions which could be imposed against it if the allegations are found to be true;

WHEREAS, MBL fully understands the terms of this Agreement and the Order ("Order") that the Assistant Secretary of Commerce for Export Enforcement will issue if she approves this Agreement as the final resolution of this matter;

WHEREAS, MBL enters into this Agreement voluntarily and with full knowledge of its rights;

WHEREAS, the parties enter into this Agreement having taken into consideration the plea agreement that MBL entered into with the U.S. Attorney for the District of Maine in the related criminal case No. 05-58-BW;

WHEREAS, MBL states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, MBL neither admits nor denies the allegations contained in the proposed charging letter;

WHEREAS, MBL wishes to settle and dispose of all matters alleged in the proposed charging letter by entering into this Agreement; and

WHEREAS, MBL agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction over MBL, under the Regulations, in connection with the matters alleged in the proposed charging letter.

2. The following sanctions shall be imposed against MBL in complete settlement of the violations of the Regulations set forth in the proposed charging letter:

- a. MBL shall be assessed a civil penalty in the amount of \$100,000, of which \$20,000 shall be paid to the U.S. Department of Commerce not later than December 1, 2005; \$20,000 shall be paid to the U.S. Department of Commerce not later than February 1, 2006; \$20,000 shall be paid to the U.S. Department of Commerce not later than June 1, 2006; \$20,000 shall be paid to the U.S.

Department of Commerce not later than September 1, 2006; and \$20,000 shall be paid to the U.S. Department of Commerce not later than December 1, 2006.

- b. The timely payment of the civil penalty agreed to in paragraph 2.a. is hereby made a condition to the granting, restoration, or continuing validity of any export license, permission, or privilege granted, or to be granted, to MBL. Failure to make timely payment of the civil penalty set forth above shall result in the denial of all of MBL's export privileges for a period of one year from the date of imposition of the penalty. The timely payment of the civil penalty is guaranteed by Lohmann Animal Health International (LAHI), a company related to MBL. LAHI and MBL are jointly and severally liable for timely payment of the fine.
- c. For a period of five years from the date of entry of the Order, MBL, its successors or assigns, and, when acting for or on behalf of MBL, its officers, representatives, agents, or employees ("Denied Person") may not participate, directly or indirectly, in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:
 - i. Applying for, obtaining, or using any license, License Exception, or export control document;
 - ii. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any

- item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or
- iii. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.
- d. BIS agrees that, as authorized by Section 766.18 (c) of the Regulations, the five year denial period set forth in paragraph 2.c. shall be suspended in its entirety for a period of 18 months from the entry of the appropriate Order, and shall thereafter be waived, provided that during the period of suspension, MBL has committed no violation of the Act or any regulation, order or license issued thereunder, and, provided further that MBL or LAHI has made timely payment of the \$100,000 civil penalty assessed pursuant to this Agreement and the Order.

3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, MBL hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, if entered), including, without limitation, any right to: (a) an administrative hearing regarding the allegations in the proposed charging letter; (b) request a refund of any civil penalty paid pursuant to this Agreement and the Order, if entered; (c) request any relief from the Order, if entered, including without limitation relief from the terms of a denial order under 15 C.F.R. § 764.3(a)(2); and (d) seek judicial review or otherwise contest the validity of this Agreement or the Order, if entered.

4. Upon entry of the Order and timely payment of the \$100,000 civil penalty, BIS will not initiate any further administrative proceeding against MBL in connection with any violation

of the Act or the Regulations arising out of the transactions identified in the proposed charging letter.

5. BIS will make the proposed charging letter, this Agreement, and the Order, if entered, available to the public.

6. This Agreement is for settlement purposes only. Therefore, if this Agreement is not accepted and the Order is not issued by the Assistant Secretary of Commerce for Export Enforcement pursuant to Section 766.18(a) of the Regulations, no Party may use this Agreement in any administrative or judicial proceeding and the Parties shall not be bound by the terms contained in this Agreement in any subsequent administrative or judicial proceeding.

7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, if entered, nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the U.S. Government with respect to the facts and circumstances addressed herein.

8. This Agreement shall become binding on BIS only if the Assistant Secretary of Commerce for Export Enforcement approves it by entering the Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

9. Each signatory affirms that he has authority to enter into this Settlement Agreement and to bind his respective party to the terms and conditions set forth herein.

BUREAU OF INDUSTRY AND SECURITY
U. S. DEPARTMENT OF COMMERCE

By:

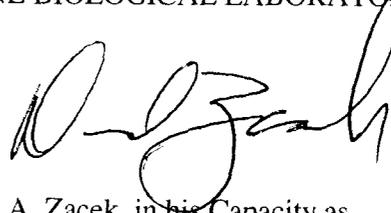


Michael D. Turner
Director
Office of Export Enforcement

Date: 10/28/05

MAINE BIOLOGICAL LABORATORIES

By:



David A. Zacek, in his Capacity as
Chief Executive Office of Maine Biological
Laboratories, Inc., and President of
Lohmann Animal Health International

Date: OCT 14, 2005

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Maine Biological Laboratories
P.O. Box 255
Waterville, ME 04901

Attn: *John Donahoe*
President

Dear Mr. Donahoe:

The Bureau of Industry and Security, United States Department of Commerce (“BIS”) has reason to believe that Maine Biological Laboratories (“MBL”) of Waterville, Maine has committed 12 violations of the Export Administration Regulations (the “Regulations”),¹ which are issued under the authority of the Export Administration Act of 1979 (the “Act”).² Specifically, BIS charges that MBL committed the following violations:

Charges 1-4 (15 C.F.R. § 764.2(a) - Exporting Avian Vaccines to Syria without the Required Department of Commerce Licenses)

As more fully described in the Schedule of Violations, which is attached hereto and incorporated herein by reference, on four occasions during the period of in or about January 2001 through in or about February 2002, MBL engaged in conduct prohibited by the Regulations by exporting avian vaccines containing the Newcastle disease virus (“vaccines”), items subject to

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2004). The violations charged occurred from 2001 through 2002. The Regulations governing the violations at issue are found in the 2001 and 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2001-2002)). The 2004 Regulations establish the procedures that apply to this matter.

² From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) (“IEEPA”). On November 13, 2000, the Act was reauthorized by Pub. L. No. 106-508, and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222, which has been extended by a Presidential Notice of August 7, 2003 (3 C.F.R., 2003 Comp. 328 (2004)), has continued the Regulations in effect under IEEPA.

the Regulations and classified under export control classification number (“ECCN”) 1C991, from the United States to Syria without Department of Commerce licenses as required by Section 742.9 of the Regulations. In so doing, MBL committed four violations of Section 764.2(a) of the Regulations.

Charge 5–8 (15 C.F.R. § 764.2(e) - Selling Avian Vaccines with Knowledge that a Violation of the Export Administration Regulations Would Occur)

On four occasions, during the period of in or about January 2001 through in or about February 2002, MBL sold or transferred vaccines, items subject to the Regulations and classified under ECCN 1C991, from the United States to an end-user in Syria with knowledge that violations of the Regulations would occur. MBL knew that a Department of Commerce license was required to export the vaccines from the United States to Syria and MBL sold or transferred the vaccines knowing that they would be exported without the required licenses. In so doing, MBL committed four violations of Section 764.2(e) of the Regulations. *See* enclosed Schedule of Violations, which is attached hereto and incorporated herein by reference.

Charges 9-11 (15 C.F.R § 764.2(g) - False Statements as to Authority to Export on Shipper’s Export Declarations)

On three occasions during the period of in or about March 2001 through in or about February 2002, MBL made false statements to the U.S. Government by filing or causing to be filed Shipper’s Export Declarations (“SED”) with the U.S. Government that stated that the vaccines being exported qualified for export from the United States to Syria as NLR (“No License Required”). These statements were false because, as described above, the exports required a license from the Department of Commerce. In so doing so, MBL committed three violations of Section 764.2(g) of the Regulations. *See* enclosed Schedule of Violations, which is attached hereto and incorporated herein by reference.

Charge 12 (15 C.F.R. § 764.2(a) - Failing to File a Shipper’s Export Declaration for an Export to Syria)

On or about January 10, 2001, MBL exported or caused the export of a vaccine, an item classified under ECCN 1C991 of the Regulations, from the United States to Syria without filing an SED. Pursuant to Section 758.1 of the Regulations as then in effect, one “must file an SED...with the United States Government for items subject to the EAR [Export Administration Regulations]...that are destined for Syria ...regardless of value....” By failing to file an SED, MBL committed one violation of Section 764.2(a) of the Regulations. *See* enclosed Schedule of Violations, which is attached hereto and incorporated herein by reference.

Accordingly, MBL is hereby notified that an administrative proceeding is instituted against it pursuant to Section 13(c) of the Act and Part 766 of the Regulations for the purpose of obtaining an order imposing administrative sanctions, including any or all of the following:

The maximum civil penalty allowed by law of \$11,000;³

Denial of export privileges; and/or

Exclusion from practice before BIS.

If MBL fails to answer the charges contained in this letter within 30 days after being served with notice of issuance of this letter, that failure will be treated as a default. (Regulations, Sections 766.6 and 766.7). If MBL defaults, the Administrative Law Judge may find the charges alleged in this letter are true without hearing or further notice to MBL. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty on each charge in this letter.

MBL is further notified that it is entitled to an agency hearing on the record if it files a written demand for one with its answer. (Regulations, Section 766.6). MBL is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent it. (Regulations, Sections 766.3(a) and 766.4).

The Regulations provide for settlement without a hearing. (Regulations, Section 766.18). Should MBL have a proposal to settle this case, MBL or its representative should transmit the offer to the attorney representing BIS named below.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, MBL's answer must be filed in accordance with the instructions in Section 766.5(a) of the Regulations with:

U.S. Coast Guard ALJ Docketing Center
40 S. Gay Street
Baltimore, Maryland 21202-4022

³ See 15 C.F.R. § 6.4(a)(2).

Maine Biological Laboratories
Proposed Charging Letter
Page 4

In addition, a copy of MBL's answer must be served on BIS at the following address:

Chief Counsel for Industry and Security
Attention: Melissa B. Mannino
Room H-3839
United States Department of Commerce
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230

Melissa B. Mannino is the attorney representing BIS in this case; any communications that you may wish to have concerning this matter should occur through her. She may be contacted by telephone at (202) 482-5301.

Sincerely,

Wendy B. Hauser
Acting Director
Office of Export Enforcement

Enclosure