

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C.**

**In the Matter of**

**CERTAIN BOTULINUM TOXIN  
PRODUCTS AND PROCESSES FOR  
MANUFACTURING OR RELATING TO  
SAME**

**Inv. No. 337-TA-1313**

**NOTICE OF INSTITUTION OF INVESTIGATION**

Institution of Investigation Pursuant to 19 U.S.C. 1337

**AGENCY:** U.S. International Trade Commission

**ACTION:** Notice

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on March 30, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Medytox Inc. of the Republic of Korea. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain botulinum toxin products and processes for manufacturing or relating to same by reason of theft and conversion and misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

**ADDRESSES:** The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

**FOR FURTHER INFORMATION CONTACT:** Pathenia M. Proctor, the Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

**SUPPLEMENTARY INFORMATION:**

**AUTHORITY:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 C.F.R. 210.10 (2021).

**SCOPE OF INVESTIGATION:** Having considered the complaint, the U.S. International Trade Commission, on April 29, 2022, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of theft and conversion and misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “botulinum toxin drug products”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is/are:

Medytox Inc.  
78, Gangni 1-gil,  
Ochang-eup, Cheongwon-gu,  
Cheongju-si, Chungcheongbuk-do,  
Republic of Korea

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Hugel, Inc.  
7, Samseong-ro 133-gil  
Gangnam-gu, Seoul  
Republic of Korea

Hugel America, Inc.  
9070 Irvine Center Drive, Suite 135  
Irvine, California 92618

Croma Pharma GmbH  
Cromazeile 2  
2100 Leobendorf  
Austria

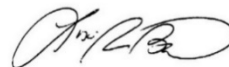
(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), as amended in 85 Fed. Reg. 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.



Lisa R. Barton  
Secretary to the Commission

Issued: May 2, 2022

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**In the Matter of**


**CERTAIN BOTULINUM TOXIN  
PRODUCTS AND PROCESSES FOR  
MANUFACTURING OR RELATING TO  
SAME**

**Inv. No. 337-TA-1313**

**DESIGNATION OF OUII ATTORNEY  
FOR SERVICE OF PROCESS**

The Office of Unfair Import Investigations (OUII) hereby designates Megan Wantland, Esq. (202) 205-3196, [Megan.Wantland@usitc.gov](mailto:Megan.Wantland@usitc.gov), as OUII's lead attorney for service of process. It is requested that all documents served by the Commission or filed by the parties in the above-referenced investigation be served upon this attorney.

Respectfully submitted,



Margaret Macdonald, Director

**OFFICE OF UNFAIR IMPORT INVESTIGATIONS**  
U.S. International Trade Commission  
500 E Street, S.W., Suite 401  
Washington, D.C. 20436  
(202) 205-2560  
(202) 205-2158 (facsimile)

April 29, 2022

**CERTAIN BOTULINUM TOXIN PRODUCTS AND  
PROCESSES FOR MANUFACTURING OR RELATING TO  
SAME**

**Inv. No. 337-TA-1313**

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **INSTITUTION OF INVESTIGATION** has been served via EDIS upon the Commission Investigative Attorney, **Megan Wantland, Esq.**, and the following parties as indicated, on **May 2, 2022**.



Lisa R. Barton, Secretary  
U.S. International Trade Commission  
500 E Street, SW, Room 112  
Washington, DC 20436

**Complainant:**

Medytox Inc.  
78, Gangni 1-gil,  
Ochang-eup, Cheongwon-gu,  
Cheongju-si, Chungcheongbuk-do,  
Korea

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

**On Behalf of Complainant:**

David Bilsker, Esq.  
**QUINN EMANUEL URQUHART & SULLIVAN LLP**  
50 California Street, 22<sup>nd</sup> Floor  
San Francisco, CA 94111  
Email: davidbilsker@quinnemanuel.com

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

**Respondents:**

Hugel, Inc.  
7, Samseong-ro 133-gil  
Gangnam-gu, Seoul  
Republic of Korea

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

**CERTAIN BOTULINUM TOXIN PRODUCTS AND  
PROCESSES FOR MANUFACTURING OR RELATING TO  
SAME**

**Inv. No. 337-TA-1313**

Certificate of Service – Page 2

Hugel America, Inc.  
9070 Irvine Center Drive, Suite 135  
Irvine, CA 92618

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

Croma Pharma GmbH  
Cromazeile 2  
2100 Leobendorf  
Austria

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

**Embassy:**

Embassy of Korea  
2450 Massachusetts Avenue  
NW Washington, DC 20008

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Service to Be  
Completed by Complainant

Embassy of Austria  
3524 International Court,  
NW Washington, DC 20008

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Service to Be  
Completed by Complainant

**Government Agencies:**

Lynda Marshall  
International Section, Antitrust Division  
U.S. Department of Justice  
450 5th Street NW, Room 11000  
Washington, DC 20530

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

**CERTAIN BOTULINUM TOXIN PRODUCTS AND  
PROCESSES FOR MANUFACTURING OR RELATING TO  
SAME**

**Inv. No. 337-TA-1313**

Certificate of Service – Page 3

Dax Terrill, Chief  
Exclusion Order Enforcement Branch  
U.S. Customs and Border Protection  
Regulations and Rulings  
90 K Street NE – 10th Floor  
Washington, DC 20229

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

Elizabeth Kraus, Deputy Director  
International Antitrust, Office of International Affairs  
Federal Trade Commission  
600 Pennsylvania Avenue, Room 498  
Washington, DC 20580

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: Email Notification  
of Availability for Download

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
National Institutes of Health  
31 Center Drive  
Bldg. 31, Rm. 47  
Bethesda, MD 20892

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
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of Availability for Download



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Alex Lasher  
Quinn Emanuel Urquhart & Sullivan, LLP  
1300 I Street, NW Suite 900  
Washington, DC 20005

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Alex Lasher:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials





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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Medytox Inc.  
78, Gangni 1-gil, Ochang-eup, Cheongwon-gu,  
Cheongju-si, Chungcheongbuk-do,  
South Korea

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Hugel, Inc.  
7, Samseong-ro 133-gil  
Gangnam-gu  
Seoul, South Korea

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). **Hugel, Inc.** is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Hugel America, Inc.  
9070 Irvine Center Drive Suite 135  
Irvine, CA 92618

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). **Hugel America, Inc.** is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Croma Pharma GmbH  
Cromazeile 2  
2100 Leobendorf, Austria

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). **Croma Pharma GmbH** is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

Sincerely,

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Embassy of the Republic of Korea  
2450 Massachusetts Ave NW  
Washington DC 20008

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). One or more of the parties named in the investigation is located in the **Republic of Korea**.

Pursuant to Commission Rule 210.11(a) (3), we are hereby serving you with a copy of the Complaint filed in this investigation together with a copy of the Commission's Notice of Investigation.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosures:

1. Complaint
2. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Embassy of Austria  
3524 International Court, NW  
Washington DC 20008

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Inv. No. 337-TA-1313**

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). One or more of the parties named in the investigation is located in **Austria**.

Pursuant to Commission Rule 210.11(a) (3), we are hereby serving you with a copy of the Complaint filed in this investigation together with a copy of the Commission's Notice of Investigation.

Sincerely,

A handwritten signature in black ink, appearing to be "A. B.", written in a cursive style.

Secretary

Enclosures:

1. Complaint
2. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Lynda Marshall  
International Section  
Antitrust Division  
U.S. Dept of Justice  
450 5th Street NW, Room 11000  
Washington, DC 20530

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Lynda Marshall:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Dax Terrill, Chief  
Exclusion Order Enforcement Branch  
U.S. Customs and Border Protection  
Regulations and Rulings  
90 K Street NE, 10th Floor  
Washington, DC 20229-1177

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Dax Terrill:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation





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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Elizabeth Kraus, Deputy Director  
International Antitrust, Office of  
International Affairs  
Federal Trade Commission  
600 Pennsylvania Avenue, Room 498  
Washington, DC 20580

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Elizabeth Kraus:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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WASHINGTON, DC 20436

May 2, 2022

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
National Institutes of Health  
31 Center Drive  
Building 31, Room 47  
Bethesda, MD 20892

**Re: Certain Botulinum Toxin Products and Processes for Manufacturing or  
Relating to Same; Inv. No. 337-TA-1313**

Dear Dale Berkley:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary

Enclosure:

1. Notice of Investigation