Message

From: AirAction [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA78B989233840789 95E04A73D258D83-AIRACTION]
Sent: 4/2/2025 11:49:01 AM
To: Ray O'Hara [rohara@busseinc.com]
CC: Jane Cardinale [janeblosom@gmail.com]; Muhamad Ansari [mansari@busseinc.com]; Ronald Kramer [rkramer@busseinc.com]
Subject: CORRECTION: Updated email address for CBI related to the Presidential Exemption

In the previous email, an incorrect email address was provided for the submission of electronic Confidential Business Information (CBI). The email address should be:

OAQPS_CBI@epa.gov

Thank you.

From: AirAction
Sent: Friday, March 28, 2025 12:30 PM
To: Ray O'Hara <rohara@busseinc.com>
Cc: Jane Cardinale <janeblosom@gmail.com>; Muhamad Ansari <mansari@busseinc.com>; Ronald Kramer <rkramer@busseinc.com>
Subject: RE: Presidential Exemption: Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP) : Long Island Sterilization

Thank you for emailing the AirAction mailbox to request a Presidential Exemption under section 112(i)(4) of the Clean Air Act and for engaging with EPA in advancing President Trump's Executive Orders and Powering the Great American Comeback. We have received your email and will be in contact soon. If you have Confidential Business Information (CBI) that you'd like to submit, please submit it in electronic version to the CBI@epa.gov inbox or in hardcopy to:

USEPA, OAQPS
CORE CBI Office
4930 Old Page Road
Durham, NC 27703

From: Ray O'Hara <rohara@busseinc.com>
Sent: Friday, March 28, 2025 12:26 PM
To: AirAction <AirAction@epa.gov>
Cc: Ray O'Hara <rohara@busseinc.com>; Jane Cardinale <janeblosom@gmail.com>; Muhamad Ansari <mansari@busseinc.com>; Ronald Kramer <rkramer@busseinc.com>
Subject: Presidential Exemption: Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP) : Long Island Sterilization
Importance: High

To whom it may concern,

We are requesting a Presidential Exemption for Ethylene Oxide Emissions Standards for Sterilization Facilities: **National Emission Standards for Hazardous Air Pollutants (NESHAP)**.

This would be for our ETO sterilizing facility: Long Island Sterilization.

Long Island Sterilization has common ownership with our medical device manufacturing company, Robert Busse & Co. dba Busse Hospital Disposables.

Busse Hospital Disposables (Busse) is a small woman owned company located in the Hauppauge Industrial Park located in Hauppauge, NY. our facilities are located two blocks from each other.

Busse Hospital Disposables is in direct control of Long Island Sterilization (LIS) , we have been sterilizing medical devices for over 26 years.

We are currently operating under a permit from the New York DEC. We have applied for an extension for our permit to take us into next year.

We are currently in full compliance with NYS DEC regulations but will need to start upgrading our sterilization facility to be incompliance with the NESHAP rules.

Busse Hospital Disposables & LIS injection mold, assemble, package and sterilize over 18 million medical products / yr.

Busse has been in operation as a manufacturer for over 45 years and in business for over 60 years.

We currently have 260 full time employees.

Our products are used throughout the entire healthcare spectrum from Hospitals to Ambulatory Centers, Doctors offices and nursing homes

We currently have a Federal Supply Schedule contract with VA Health system.

Most of the sales of our products are done through our distributors such as Cardinal Health, Medline Industries, Henry Schein, McKesson Medical, Owens & Minor and over 100 local and regional distributors.

We also export our medical devices overseas.

Along with a full line of single use, procedural kits & trays, surgical drapes and OR suction products under the Busse brand, we also manufacture private branded products for many well-known companies in the US.

We also manufacture OEM parts to other medical device manufacturers for use in their sterile procedural kits, trays & surgical packs.

We are requesting a period of at least two years to become compliant with the new NESHAP regulations. We are asking this because:

1) We feel the necessary upgrades to our existing equipment along with new construction in our facility will be quite costly for our company.
2) There will also be a required purchase of additional monitoring equipment. This will be a very large capital expense for us and most be done in stages for cash flow as well as staying in successful day to day operation as a business. The technology exists but is not inexpensive.

One of the bullet points you ask us to include was explanation as to why this extension "is in the national security interest of the United States".

I believe the best we can say is simply that we manufacture and sell at an average over 18 million sterile medical devices annually. 98% are sold to be used in the United Sates.

Lastly, many of our products are used during lifesaving surgeries as well as being used in the normal Emergency Room's and physician's offices throughout the United States.

I hope that we have answered your questions to your satisfaction and hope you can help us by including us in this program.

If you need any additional information or would like to visit our two facilities just let me know.

Sincerely,

Ray

Ray O'Hara
Vice President

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Hauppauge, NY 11788
800-645-6526 ext. 242
www.busseinc.com

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