

	<h2 style="text-align: center;">Medical Gas Compliance Alert</h2>
<p>31 January 2013 rev. 7/14/2015</p>	<h3 style="text-align: center;">Medical Gas Certification</h3>

Important Compliance Alert – Medical Gas Certification

This GAWDA Medical Gas Compliance Alert is to inform GAWDA members that the FDA has developed a process to remove the “unapproved medical gas” label from certain drug listings. Before this process was implemented, the drug listing for medical gases looked like this:

Category HUMAN PRESCRIPTION DRUG LABEL	DEA Schedule	Marketing Status unapproved medical gas
<p>NOTE: THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE, AND THIS LABELING HAS NOT BEEN APPROVED BY FDA. For further information about unapproved drugs, click here.</p>		

Now the drug listing can look like this:

Category HUMAN PRESCRIPTION DRUG LABEL	DEA Schedule	Marketing Status New Drug Application
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Basically, it is now possible to remove the FDA safety warning from our medical gas drug listings.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. Among other provisions, FDASIA:

1. Provided approval status for “designated medical gases”
2. Assured Drug User Fees are NOT applied to medical gases
3. Provided a framework to develop/revise medical gas regulations

Congress designated the core medical gases (and their "medically appropriate" mixtures) to have status similar to “approved” drugs. These gases are oxygen, nitrogen, air, helium, carbon dioxide, nitrous oxide and carbon monoxide. In order to grant approval status to these drug gases, the FDA uses an application and “certification” process in place of the very expensive “New Drug Application” (NDA). For the full text of the FDA instructions on this subject, see the draft “Guidance for Industry - Certification Process for Designated Medical Gases.” -

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332136.pdf>

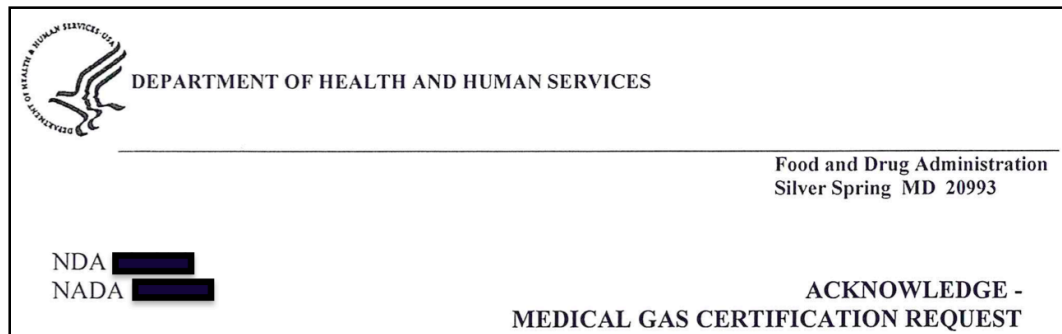
This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Key points of the new process:

1. **Definitions** - The draft process creates two types of medical gas manufacturers: the “Original Manufacturer” and the “Subsequent Manufacturer”.
 - a. As the title suggests, the original manufacturer is the firm that first puts the gas into medical grade. For oxygen and nitrogen, it is the Air Separation Unit (ASU) that produces the bulk oxygen, USP and nitrogen, NF. For carbon dioxide, helium and nitrous oxide, the original manufacturer will be the validated plant that produced the product from the non-medical raw material. There are a few GAWDA members who own Air Separation Plants that produce O₂, USP and N₂, NF and these members are “original manufacturers”.
 - b. The subsequent manufacturers are the firms that receive the medical product (gas or liquid) from another plant. That other plant could be the original manufacturer or even another subsequent manufacturer. Most GAWDA members who fill medical gases are “subsequent manufacturers”.
 - c. Air, USP is a special case for the definitions of original and subsequent manufacturer:
 - i. If you fill medical air with an air compressor, then you are an original manufacturer since you are the first firm to put that gas into medical gas service.
 - ii. If you fill medical air by blending the oxygen, USP and nitrogen, NF, then you are a subsequent manufacturer since you are creating a "medically appropriate" mixture of designated medical gases by blending components that have been produced by an original manufacturer.
 - d. Medical gas mixtures – if you produce medical gas mixtures and you are not the original manufacturer of the components, you are a subsequent manufacturer for those mixtures.
 - e. NDA/NADA – New Drug Application and New Animal Drug Application

2. The Certification Process –

- a. For original manufacturers – you submit an application (see the guidance) to the FDA. The FDA will consider your application and respond to your request. If successful, the title of the FDA response letter will be “ACKNOWLEDGE – MEDICAL GAS CERTIFICATION REQUEST” and there will be a New Drug Application (NDA/NADA) number on the top of the letter. The FDA has 60 days to approve your certification request. In the absence of such approval or denial you are considered certified.



- b. For subsequent manufacturers – Although you still must continue to register your facility and list your drugs, you are not required to complete an application for certification. Based on discussions with the FDA on 10 Jan 2014, you use the NDA/NADA number of your supplier. If you have more than one supplier for a designated medical gas, FDA indicated that you should select your primary supplier’s NDA/NADA. If you are making medical gas mixtures, FDA suggests that you select the NDA/NADA number for one of the ingredients in the mixture.

3. How do I remove the “unapproved medical gas” warning from my drug listing?

- a. For original manufacturers –
 - i. In the Spring of 2013, you should have completed the medical gas certification application. (If you still need to complete the application, let us know.)
 - ii. The FDA should have sent you a letter titled “Acknowledge – Medical Gas Certification Request”. This letter should have included an NDA/NADA number.
 - iii. Resubmit your listing for medical air and add the NDA/NADA number in the pull down menu.

- iv. If AsteRisk, or another company, processed your FDA Drug Listing, have them resubmit your listing with the NDA/NADA number to remove the unapproved medical gas distinction.
 - b. For subsequent manufacturers (most GAWDA members who fill medical gases), the FDA instructs that you should:
 - i. Ask your bulk medical gas supplier for their NDA/NADA number on each bulk medical gas that you buy.
 - ii. Update your drug product listing with your supplier's NDA/NADA number.
- 4. Do I need both the NDA and NADA?**
 - a. If you only sell medical gases for human use, you only need the NDA number.
 - b. If your medical gases are also used for animal use, you will also need the NADA number.
 - i. You will need to submit a separate drug listing for the medical gases for animal usage (using the NADA number).
- 5. How can I verify that my FDA drug listing has been updated?**
 - a. Log on to: <http://dailymed.nlm.nih.gov/dailymed/search.cfm>
 - b. Enter your labeler code in the search window and all of your drug listings will be displayed.

If you have questions about this, or other FDA issues, please contact Tom Badstubner: tom@asteriskllc.com.

Attachment 1 - NDA/NADA Number Listings

If your bulk medical gas supplier is listed below, you can update your own drug listings to remove the “unapproved medical gas” statement and safety warnings.

If AsteRisk or another registration/listing service processes your electronic submissions to the FDA, simply indicate your bulk medical gas supplier and send this form to the service.

For AsteRisk, fax to 1-508-883-3558 or send to tom@asteriskllc.com

Your Name: _____ Company: _____

Product	Company	NDA	NADA
Oxygen USP	<input type="checkbox"/> Air Liquide America L.P.:	205827	141398
	<input type="checkbox"/> Air Liquide Industrial U.S. LP:	205712	141354
	<input type="checkbox"/> Air Liquide Large Industries U.S. LP:	205737	141358
	<input type="checkbox"/> Air Products:	205865	141396
	<input type="checkbox"/> Airgas Merchant Gases, LLC:	205840	141382
	<input type="checkbox"/> AIRGAS USA, LLC:	206023	141413
	<input type="checkbox"/> Linde Canada LTD:	205817	141373
	<input type="checkbox"/> Linde Gas Puerto Rico Inc.:	205818	141374
	<input type="checkbox"/> Linde LLC:	205767	141365
	<input type="checkbox"/> Matheson:	205889	141399
	<input type="checkbox"/> Praxair Canada:	205986	141408
	<input type="checkbox"/> Praxair USA:	205849	141387
Nitrogen NF	<input type="checkbox"/> Air Liquide America L.P.:	205829	141380
	<input type="checkbox"/> Air Liquide Industrial U.S. LP:	205713	141357
	<input type="checkbox"/> Air Liquide Large Industries U.S. LP:	205738	141359
	<input type="checkbox"/> Air Products:	205866	141397
	<input type="checkbox"/> Airgas Merchant Gases, LLC:	205839	141381
	<input type="checkbox"/> AIRGAS USA, LLC:	206024	141414
	<input type="checkbox"/> Linde Gas Puerto Rico Inc.:	205816	141372
	<input type="checkbox"/> Linde LLC:	205766	141364
	<input type="checkbox"/> Matheson Tri-Gas:	205891	141401
	<input type="checkbox"/> Praxair Canada:	205985	141407
	<input type="checkbox"/> Praxair USA:	205850	141388
	CO2 USP	<input type="checkbox"/> Airgas Carbonic, Inc:	205846
<input type="checkbox"/> AIRGAS USA, LLC:		206025	141415
<input type="checkbox"/> Linde LLC:		205764	141362
<input type="checkbox"/> Linde Merchant Production, Inc.:		205815	141371
<input type="checkbox"/> Praxair USA:		205852	141390
Helium USP	Air Liquide Healthcare America Corporation:	206026	141416
	<input type="checkbox"/> Air Products:	205864	141395
	<input type="checkbox"/> AIRGAS USA, LLC:	205843	141383
	<input type="checkbox"/> Praxair Distribution-USA:	205912	141405
	<input type="checkbox"/> Praxair Mid-Atlantic LLC. USA:	205911	141404
	<input type="checkbox"/> Praxair USA:	205851	141389
N2O USP	<input type="checkbox"/> Air Liquide America Specialty Gases LLC:	205704	141350
	<input type="checkbox"/> Nitrous Oxide Corporation:	206009	141411
	<input type="checkbox"/> Nitrous Oxide of Canada:	206014	141412

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Attachment 2 - Sample NDA/NADA Number Request Letter

If your bulk medical gas supplier is not listed in Attachment 1, you will need to ask your supplier for their NDA/NADA numbers. After you receive the NDA/NADA numbers from your supplier, you can update your own drug listings to remove the “unapproved medical gas” statement and safety warnings.

{{{Your Letterhead}}}

Date: XXXX

To: {{{Your Medical Gas Supplier}}}

In accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), July 9, 2012, we are updating our medical gas listings to remove the “unapproved medical gas” statement on our listings.

We are purchasing the following bulk designated medical gases from your firm and using them in our manufacturing process:

- | | | |
|--|------------|-------------|
| <input type="checkbox"/> Oxygen, USP | NDA: _____ | NADA: _____ |
| <input type="checkbox"/> Nitrogen, NF | NDA: _____ | NADA: _____ |
| <input type="checkbox"/> Carbon Dioxide, USP | NDA: _____ | NADA: _____ |
| <input type="checkbox"/> Nitrous Oxide, USP | NDA: _____ | NADA: _____ |
| <input type="checkbox"/> Helium, USP | NDA: _____ | NADA: _____ |

Please insert your NDA and NADA number for each of the medical gases indicated above. We will update our medical gas listings with these NDA/NADA numbers.

Thank you,

{{{Your name}}}