GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION	**Medical Gas Compliance Alert**
31 January 2013	***Medical Gas Certification***

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	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		unapproved medical gas

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.

Now the drug listing can look like this:

Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		New Drug Application

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:

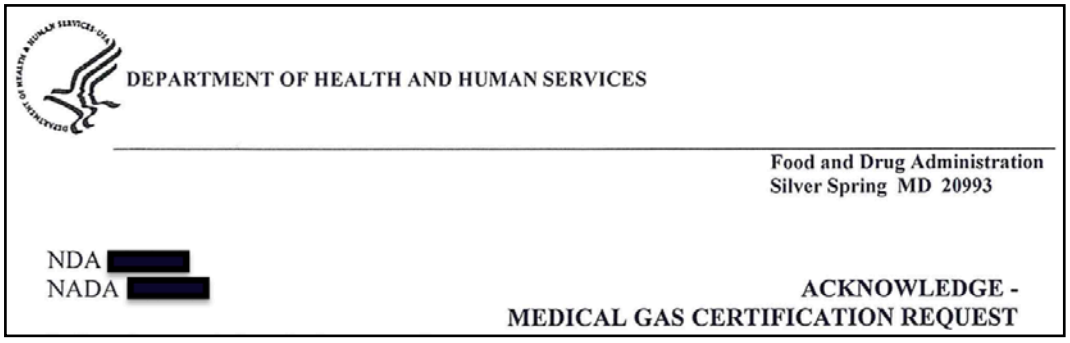
1. Provided approval status for "designated medical gases"
2. Assured Drug User Fees are NOT applied to medical gases
3. Provided a framework to develop/revise medical gas regulations

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

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 O_2, USP and N_2, 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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA [redacted]
NADA [redacted]

ACKNOWLEDGE -
MEDICAL GAS CERTIFICATION REQUEST

    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	❑	Air Liquide America L.P.:	205827	141398
	❑	Air Liquide Industrial U.S. LP:	205712	141354
	❑	Air Liquide Large Industries U.S. LP:	205737	141358
	❑	Air Products:	205865	141396
	❑	Airgas Merchant Gases, LLC:	205840	141382
	❑	AIRGAS USA, LLC:	206023	141413
	❑	Linde Canada LTD:	205817	141373
	❑	Linde Gas Puerto Rico Inc.:	205818	141374
	❑	Linde LLC:	205767	141365
	❑	Matheson:	205889	141399
	❑	Praxair Canada:	205986	141408
	❑	Praxair USA:	205849	141387
Nitrogen NF	❑	Air Liquide America L.P.:	205829	141380
	❑	Air Liquide Industrial U.S. LP:	205713	141357
	❑	Air Liquide Large Industries U.S. LP:	205738	141359
	❑	Air Products:	205866	141397
	❑	Airgas Merchant Gases, LLC:	205840	141382
	❑	AIRGAS USA, LLC:	206024	141414
	❑	Linde Gas Puerto Rico Inc.:	205816	141372
	❑	Linde LLC:	205766	141364
	❑	Matheson Tri-Gas:	205891	141401
	❑	Praxair Canada:	205985	141407
	❑	Praxair USA:	205850	141388
CO2 USP	❑	Airgas Carbonic, Inc:	205846	141385
	❑	AIRGAS USA, LLC:	206025	141415
	❑	Linde LLC:	205764	141362
	❑	Linde Merchant Production, Inc.:	205815	141371
	❑	Praxair USA:	205852	141390
Helium USP	❑	Air Liquide Healthcare America Corporation:	206026	141416
	❑	Air Products:	205864	141395
	❑	AIRGAS USA, LLC:	205839	141381
	❑	Praxair Distribution-USA:	205912	141405
	❑	Praxair Mid-Atlantic LLC. USA:	205911	141404
	❑	Praxair USA:	205851	141389
N2O USP	❑	Air Liquide America Specialty Gases LLC:	205704	141350
	❑	Nitrous Oxide Corporation:	206009	141411
	❑	Nitrous Oxide of Canada:	206014	141412

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:

❑ Oxygen, USP	NDA: _____	NADA:_____
❑ Nitrogen, NF	NDA: _____	NADA:_____
❑ Carbon Dioxide, USP	NDA: _____	NADA:_____
❑ Nitrous Oxide, USP	NDA: _____	NADA:_____
❑ 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}}}