Appendix A: Medical Gas Partnership Agreement

I. PURPOSE AND GOALS

This Partnership Agreement (Agreement) establishes a cooperative program between two entities (individually a Party -- collectively the Parties):

The Food and Drug Administration (FDA) _____ (District)

AND

The _____ (the State Agency) in the State of _____ (the State).[1]

The Agreement sets forth working arrangements between the Parties for: regulatory planning; inspections; compliance and emergency response activities; information sharing; and training, including an agreement on the number of medical gas inspections to be conducted by the State Agency.

Through joint planning and coordination of efforts, the Parties seek to enhance overall consumer protection while reducing duplicative effort and achieving more efficient use of combined resources.

II. BACKGROUND

The Parties have entered into this Agreement in mutual recognition of the need to: conserve resources; more effectively and efficiently use personnel and equipment; exchange information of mutual interest in a timely manner and according to law; and to the extent practicable, reduce duplicative inspectional and regulatory efforts in times of restricted resources. It is understood that each Party will continue to exercise its own jurisdictional authorities and enforcement discretion, and that the cooperation the Parties extend to one another does not include transfer of any jurisdictional authority or responsibilities.

III. PROGRAM COMPONENTS AND ACTIVITIES

A. Joint Planning

The Parties will hold an annual planning meeting to assess coordination efforts and determine whether any adjustments may be appropriate. In addition to any other agenda items, these meetings, will include an update by each Party on its general inspection programs and on any changes of laws or policies that might affect implementation of the

[1] For purposes of this Agreement, the term "State" means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Tribal agencies or any territory or possession of the United States.

Agreement, and a determination of which establishments each Party will inspect over the next twelve month period. Examples of additional topics of discussion include: the Parties' respective sampling programs for medical gas products; sampling to be initiated during the next twelve month period; and training needs.

B. Joint Inspections

FDA and the State Agency will notify each other prior to conducting any inspection related to a medical gas product in the jurisdiction of the State Agency. The State Agency will advise FDA if it wishes to accompany FDA on any such FDA inspections and FDA will do the same for such inspections by the State Agency. Implementation of such joint inspections will depend on the availability of personnel and the lead Party's priorities.

C. Compliance Activities

The State Agency agrees to inspect at least ___ % or _____ (number of facilities) of the medical gas facilities within its jurisdiction each year. During the annual planning meeting, the FDA and the State Agency will select facilities to inspect in accordance with any inspection priorities agreed upon by the Parties.

D. Information Exchange

1. In addition to any information the State Agency otherwise provides to FDA under this Agreement, the State Agency will provide to FDA the following documents annually or on such other schedule(s) as the Parties may agree upon in writing:

a. Copies of any letters or notices issued by the State Agency to detain or embargo any medical gas product(s);
b. Licensing and registration notices issued by the State Agency, including notices of proposed or actual revocation or suspension of licenses or registrations, for medical gas products and facilities;
c. Notification of all litigation concerning medical gases to which the State Agency is a party;
d. Correspondence by or to the State Agency addressing regulatory matters issued to, received from, or expressly addressing any medical gas product manufacturers, fillers, transfillers, cascaders, transferors, wholesalers, or distributors;
e. Any letters or other notices from the State Agency to a medical gas facility concerning violations; and
f. Notification of all other regulatory actions, including announcements or applications of new regulatory interpretations specifically addressing medical gases. This notification may be achieved by providing copies of annual summaries and individual reports by the State Agency discussing the specific action.

2. In addition to any information FDA otherwise provides to the State Agency under this Agreement, FDA will provide to the State Agency annually, or on such other schedule(s)

as the Parties may agree in writing, the following documents specifically addressing medical gas facilities, or the medical gas products of facilities, in the jurisdiction of the State Agency:

a. Copies of Warning or untitled letters issued by FDA;
b. Notices issued by FDA of administrative sanctions, such as citations and Section 305 Meetings;
c. Complaints filed by or against FDA; and
d. Notification of all litigation to which FDA is a Party concerning such medical gas facilities.

3. Both Parties agree to work toward greater use of electronic ("paperless") means to exchange and share information.

E. Disasters

Each Party will provide, upon request, names, titles, and telephone numbers of disaster and back-up coordinators. In the event of a disaster, such as a flood, hurricane, fire, common carrier accident, or chemical spill, affecting medical gas facilities or products within the jurisdiction of the State Agency, each Party may request assistance from the other.

F. Recalls

Each Party will provide to the other information concerning recalls or product corrections for medical gas products. Such notification will generally be made through the Federal-State electronic communication system.

G. Training

Training may be requested by either Party with the understanding that the ability to fulfill such a request will depend on the availability of personnel and resources as well as priorities of the responding Party. Training courses by FDA or any other training needs will be addressed in the annual planning report and/or meeting. Partnership funds provided to the FDA District may be used to support training activities.

H. Exchange of Inspectional Information

The Parties will exchange Official Establishment Inventories or other appropriate lists of medical gas facilities and cover sheets or summaries of inspection reports addressing medical gas facilities, or the medical gas products of facilities, in the jurisdiction of the State Agency. Each Party will provide full inspection reports upon request to the other Party to reduce duplication of effort.

I. Complaints

The Parties will endeavor to notify each other and coordinate their investigations of consumer and industry complaints consisting of reports of real and/or potential personal injury or deaths related to medical gases. For any reports of a death or injury, the parties should notify each other within 24 hours of receiving the report; all other reports should be shared annually.

J. Confidentiality

1. Any information released to either Party is provided for the sole purpose of furthering the investigatory functions and cooperative law enforcement and regulatory efforts of the Parties. The Parties understand that some of the information each receives from the other may be information exempt from public disclosure under Federal laws and regulations -- non-public information such as: confidential commercial information; trade secret information that the Parties will share only as permitted by law; personal privacy information; law enforcement information; or internal, pre-decisional information.

2. Before obtaining any non-public information from FDA under this Agreement, the State Agency must provide FDA with a confidentiality commitment satisfying the requirements of 21 C.F.R. 20.88(d) ("20.88 Confidentiality Commitment"). If an employee of the State Agency is commissioned by FDA in accordance with 21 U.S.C. 372(a) receives Non-public Information from FDA, or under the authority of FDA but not under the authority of the State Agency, that individual may not share any such information with the State Agency unless the information falls within the scope of a 20.88 Confidentiality Commitment. To the extent that the terms of a 20.88 Confidentiality Commitment conflict with those of this section of this Agreement, the terms of the 20.88 Confidentiality Commitment will prevail.

3. Each Party agrees not to publicly disclose non-public information provided by the other Party without the prior written authorization of the sharing Party or a prior written statement from the sharing Party that the information no longer has non-public status. Public disclosure includes, but is not limited to, sharing of information with other State agencies and introduction of information in court without a protective order.

4. The receiving Party will inform the sharing Party immediately of any effort made to obtain the sharing Party's non-public information from the receiving Party by and/or through a court or other government body of competent jurisdiction. If such a body orders disclosure of the sharing Party's non-public information, the receiving Party will take appropriate measures within its control in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

5. Any other provisions of this Agreement notwithstanding, FDA will not provide the State Agency access to any document or information to the extent that providing such access would place the FDA in breach of 18 U.S.C. sec. 1905 (Trade Secrets Act), 5 U.S.C. sec. 552a (Privacy Act), 21 U.S.C. sec. 331(j) (Federal Food, Drug, and Cosmetic Act), FDA regulations, or any other Federal law or regulation.

K. Funding

Each Party is responsible for funding its own inspection and enforcement activities under this Agreement. FDA partnership funds, if available, may be used to support training, travel to meetings, or equipment for the State Agency.

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

V. LIAISON OFFICERS

VI. ASSESSMENT MECHANISMS

This Agreement will be effective for one year from the date of signature by the later Party to sign it. At the end of that year and, annually thereafter as long as the Agreement remains in force, the Parties will evaluate the effectiveness of the Agreement in meeting their goals and may amend the Agreement, continue it as written, or dissolve the Agreement by mutual consent. In addition, at any time, the Parties may modify or terminate the Agreement by mutual written consent, and either Party may terminate the Agreement by means of a written notice of termination.

VII. SIGNATURES OF RESPONSIBLE PARTIES

APPROVED AND ACCEPTED FOR THE STATE OF _____

By: _____

Title: _____

Date: _____

APPROVED AND ACCEPTED FOR THE U.S. FOOD & DRUG ADMINISTRATION

By: _____

Title: _____

Date: _____