INSTRUCTIONS FOR SUBMITTING REQUEST FOR CERTIFICATION OF DESIGNATED MEDICAL GAS USING FORM FDA 3864

1. **APPLICANT INFORMATION:** The name and contact information of the legal person submitting the certification request should be provided in the indicated areas. For non-U.S. applicants the name and contact information of the legal person who resides or maintains a place of business within the U.S. and is authorized to represent the applicant should be entered in the "Contact Information" field.

2. **TYPE OF SUBMISSION:** The submission type should be indicated by checking the appropriate box.

   Original Certification Request – An initial request submitted by an applicant for certification of a medical gas as a designated medical gas.

   Amendment to a Pending Certification Request – Any submission related to a pending submission that revises existing information or provides additional information, including responses to Information Request Letters.

   Resubmission – Any complete submission that has been revised and submitted again following a previous denial.

   Supplement to a Granted Certification – Any submission that contains a change to a granted certification.

   Other – Any submission that does not fit in one of the other categories.

   For original certification requests, the requester should check the appropriate box identifying the type of application requested (NDA, NADA, or both). For requests that are not original certification requests, the NDA and/or NADA number should also be provided if one exists. If any box other than the "original certification request" box is checked an explanation should be provided in the "Reason for Submission" block (e.g., "Response to 02/15/13 Information Request Letter", "Change of applicant or contact information", or "Notification of a change to manufacturing facility information").

3. **DESCRIPTION OF MEDICAL GAS:** The requestor should check the box to select the gas to which the request applies. The requestor will certify in section 7 that the gas satisfies the applicable compendial standard.

4. **FACILITY INFORMATION:** Only a brief description sufficient to enable FDA to understand the role of each facility where the designated medical gas to which this request applies will be initially produced need be provided in this section. For example, "production of [gas] by physical separation" or "production of [gas] by purification." If a unique facility identifier (e.g., a DUNS Number) for a facility has not been assigned, one may be obtained for no cost directly from Dun & Bradstreet (http://www.dnb.com). If an FDA Establishment Identifier (FEI) exists for the facility it should be included. If the gas is initially produced at multiple facilities, click the "Add Continuation Page" button for additional fields.

5. **CERTIFICATION OF ADEQUATE MANUFACTURE, PROCESSING, PACKAGING, AND HOLDING OF DESIGNATED MEDICAL GAS:** The requestor must check the box to affirm that its methods, facilities, and controls used for the manufacture, processing, packaging, and holding of the gas, as applicable, are adequate to preserve the safety, identity, strength, quality, and purity of the gas (21 CFR 230.50(b)(5)).

6. **ADDITIONAL INFORMATION:** If there is any other information which FDA deems appropriate to determine whether the medical gas is a designated medical gas, or the requestor believes any other information would be useful for FDA to consider, the requester may provide that information in this section.

7. **SIGNATURE(S):** The form must be signed and dated. Ordinarily only one person should sign the form: the requestor, or the requestor's attorney, agent, or other authorized official. However, if the person signing the request does not reside or have a place of business within the United States, the request should be countersigned by an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

SUBMISSION: FDA encourages the submission of designated medical gas certification requests electronically via the CDER NextGen Portal at: https://cdernextgenportal.fda.gov. If you choose to submit your certification request via mail, send two copies of the completed, signed Form FDA 3864 to: Central Document Room, 5901B Ammendale Road, Beltsville, MD 20705.