INSTRUCTIONS FOR FILLING OUT AND SUBMITTING ANNUAL REPORT FOR DESIGNATED MEDICAL GAS USING FORM FDA 5025

1. **Applicant Information:** The name and contact information of the legal person submitting the annual report 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. **Product Information:** The applicant should select the gas that is the subject of the annual report and include the NDA and/or NADA number(s) for the gas.

3. **Annual Report Information:** The applicant should include the following information for the reporting period. If necessary, any of this information can be submitted as an attachment to the form.

   Summary of Significant New Information: A brief summary of significant new information that might affect the safety, effectiveness, or labeling of the designated medical gas, including any actions the applicant has taken or intends to take as a result of this new information.

   Distribution Data: Information about the quantity of the designated medical gas distributed by the applicant. Include the National Drug Code (NDC) numbers and the quantities distributed for domestic use and the quantities distributed for foreign use. If distribution data, including the amount of domestic and foreign distribution, is submitted under section 510(j)(3) of the FD&C Act, the submitter may alternatively reference their section 510(j)(3) report, including the date of the report.

   Administrative Changes: Any changes to the applicant's name or contact information.

   Facility Information: List all facilities at which the designated medical gas has been initially produced in the past reporting year. Check the appropriate box if it was removed or added in the past year. If submitting information on multiple facilities, click the "Add Continuation Page" button for additional fields.

4. **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 annual reports electronically via the CDER NextGen Portal at: https://cdernextgenportal.fda.gov. If you choose to submit your annual report via mail, send two copies of the completed, signed Form FDA 5025 to: Central Document Room, 5901B Ammendale Road, Beltsville, MD 20705.