



Our STN: BL 125158/297

**SUPPLEMENT APPROVAL**

August 29, 2024

Emergent Product Development Gaithersburg Inc.  
Attention: Lisa Jeffers  
3500 N. Martin Luther King Jr. Blvd  
Lansing, MI 48906-9910

Dear Ms. Jeffers:

We have approved your request received October 27, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Smallpox and Mpox (Vaccinia) Vaccine, Live (ACAM2000) manufactured at your facilities located in Canton, Massachusetts and Rockville, Maryland to include prevention of mpox disease in individuals determined to be at high risk for mpox infection.

## **LABELING**

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the Package Insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert and the draft carton and container labels submitted under amendment 14, dated August 28, 2024, and the Medication Guide submitted under amendment 15, dated August 29, 2024.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert submitted on August 28, 2024, and the Medication Guide submitted on August 29, 2024. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

## **CARTON AND CONTAINER LABELS**

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 28, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125158, at the time of use and include implementation information on Form FDA 356h.

## **ADVERTISING AND PROMOTIONAL LABELING**

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave.  
WO71–G112  
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

## **PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

We note that you have fulfilled the pediatric study requirement for ages 0 to 17 years for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Rebecca Reindel, M.D.  
Director  
Division of Clinical and Toxicology Review  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research