Our STN: BL102865.5841

SUPPLEMENT APPROVAL
July 3, 2023

GenTrac, Inc. (a Pfizer Company)
Attention: William Vogt
66 Hudson Boulevard East
New York, NY 10001

Dear Mr. Vogt:

Please refer to your supplement to your Biologics License Application (BLA) received December 15, 2023, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Thrombin, Topical (Bovine).

We also refer to our supplement approval letter dated June 16, 2023, which contained the following error:

> The letter include reference to section 8.4 Pediatric Use as part of the approval and it should not be included as it was not reviewed for any changes to the prescribing information label.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 16, 2023, the date of the original supplement approval letter.

We have approved your request received December 15, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Thrombin, Topical (Bovine), to update the prescribing information for Thrombin-JMI U.S. Package Insert (USPI). This update complies with the Pregnancy and Lactation Labeling Rule (PLLR) and includes revisions to the following sections: BOXED WARNINGS, 5 WARNINGS AND PRECAUTIONS 5.2 Thrombosis, 5.3 Immunogenicity), 8 USE IN SPECIFIC POPULATIONS, (8.1 Pregnancy, 8.2 Lactation), 13 NON-CLINICAL TOXICOLOGY (13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility).

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 5002, June 15, 2023.

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 June 15, 2023. 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 102865/0 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely,

Elizabeth Hart, MD
Acting Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research