



NDA 210867/S-003

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT**

Medicines Development for Global Health Limited
c/o Target Health LLC
Attention: Mary Shatzoff, MS, RAC
Senior Director of Regulatory Affairs
261 Madison Avenue, 24th Floor
New York, NY 10016

Dear Ms. Shatzoff:

Please refer to your supplemental new drug application (sNDA) dated and received August 28, 2020, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Moxidectin Tablets, 2 mg.

This Prior Approval supplemental new drug application provides for updates to the prescribing information (PI) based on the results of the postmarketing requirement (PMR) #3367-1, listed in the NDA approval letter dated June 13, 2018, to conduct a standard GLP pre-postnatal toxicity study in the rat with orally administered moxidectin that includes maternal evaluations and assessment of physical development, neurological function, maturation, and fertility in first-generation offspring.

Revisions have been made to the following sections of the PI: **HIGHLIGHTS, USE IN SPECIFIC POPULATIONS (8), Pregnancy (8.1) and Lactation (8.2)** subsections, **NONCLINICAL TOXICOLOGY (13), Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection, and **PATIENT COUNSELING INFORMATION (17)** section. Minor editorial changes have also been made throughout the PI.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names and PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated August 28, 2020, containing the final report for the following PMR listed in the June 13, 2018, approval letter.

- 3367-1 Conduct a standard GLP pre-postnatal toxicity study in the rat with orally administered moxidectin that includes maternal evaluations and assessment of physical development, neurological function, maturation, and fertility in first-generation offspring.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing commitment listed in the June 13, 2018, approval letter that is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kristine Park, PhD, RAC, Senior Regulatory Health Project Manager, at (301) 796-0471.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
 - Prescribing Information

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
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