U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

May 08, 2024

ACKNOWLEDGEMENT

Porton Pharma Solutions Ltd.
Attention: Stephen Wong, QA Director
Porton USA Inc.
6 Cedarbrook Dr.
Cranbury, NJ 08512

FDA Submission Tracking Number (STN): MF0001190

Dear Stephen Wong:

We received your request to establish a Tobacco Product Master File (TPMF). As of the date of this letter, your TPMF is established, assigned the above cited STN, and ready for reference by another party.

Date of Submission:	April 24, 2024
Date of Receipt:	April 24, 2024
Owner:	Porton Pharma Solutions Ltd.

This letter does not mean that the information in your TPMF is sufficient to support any other FDA submission. We only intend to review your TPMF upon receipt of a submission requesting to incorporate your information by reference (e.g., to support a pending application). We will notify you if additional information is needed.

If you wish to authorize another party to reference this information in any FDA submissions, provide them with a letter of authorization (LOA) and include the assigned STN. The LOA should specify the party authorized to reference the TPMF and what information within this TPMF is being referenced (i.e., sections, subsections, and page numbers) in support of their submission. We recommend that you also submit a copy of your LOA to FDA as an amendment to this TPMF.

It is the owner's responsibility to maintain files that are both current and accurate. Therefore, if updates are required for this TPMF, we request you promptly submit an amendment to FDA that contains the following:

- A cover letter that includes the following text in the subject line: **AMENDMENT TO MF0001190**. We request your cover letter identify the changes in the submission, identify where the changes were made (i.e., sections, subsections, and page numbers), and include a statement that there are no additional revisions;
- A current table of contents; and
- A list of each person currently authorized to reference the submission (including name, mailing address, email address, and phone number) and the extent to which each authorized person may reference the submission (i.e., sections, subsections, and page numbers).

Furthermore, we consider your amended information to supersede all previous versions. We request that you notify all persons authorized to reference this submission each time the TPMF is amended.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[1,2] using eSubmitter.[3] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[4]; if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions regarding this TPMF, please contact Corrilisha Telford, MPH, Regulatory Health Project Manager, at (301) 796-0209 or corrilisha.telford@fda.hhs.gov.

Sincerely,

Digitally signed by Marcella W. Dolling -S
Date: 2024.05.08 09:24:38 -04'00'

Marcella Dolling, M.S., M.B.A.
Chief, Regulatory Project Management Branch I
Division of Regulatory Project Management
Office of Science
Center for Tobacco Products

[1] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[2] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[3] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter
[4] See https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp