Health Canada Santé Canada

Health Canada
Therapeutic Products Directorate
DMF Administration Unit
Address Locator 0201D
101 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9
Canada

DMF 2013-063

OF2-28-11-2013063

April 4, 2013

Mr. B. V. Satyanarayana
Director
CHEMIPACK (INDIA) PRIVATE LIMITED
8-3-166/6 & 7, II Floor
Sree Arcade, Erragadda
Hyderabad, 500018
India

Dear Mr. Satyanarayana:

RE: HDPE Bottles

We are acknowledging receipt of your letter dated **September 10, 2012** and the material listed below for HDPE Bottles, which has been assigned the number DMF 2013-063.

Drug Master Files (DMFs) will only be reviewed in connection with drug submissions from sponsors for whom you have provided a letter of authorization; therefore, this acknowledgement should not be considered as an approval of the content of your Drug Master File.

Please note that Health Canada has received the following:

1. Payment of **$400.00 Cdn.** for new Drug Master File registration
2. 2 binder(s)
3. Statement of commitment
4. BSE/TSE attestation

Please refer to the Health Canada website for the new amended fees as of April 1st, 2012, including the stipulation of a new two percent annual increase effective each April 1st.
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/index-eng.php#master

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Health Canada is moving toward an electronic format for Drug Master Files; as such, we would appreciate a copy of your Drug Master File(s) and subsequent updates to be sent as PDF files on a CD to supplement the paper copy. Please also include an attestation confirming the hard copy is identical to the electronic copy.

We would like to take this opportunity to remind DMF Owners and Agents that they are responsible for all costs associated with shipping documents and electronic information to Health Canada, including any applicable customs and/or brokerage fees. Packages must indicate "**Terms DDP (Delivered Duty Paid)**". Any packages submitted to Health Canada with a request for additional charges by a shipper or brokerage firm will be returned to sender at the sender's expense. Thank you for your attention to this matter.

For Type I DMFs (pertaining to active pharmaceutical ingredients), you are reminded that a copy of the open part must be provided to the sponsor of a drug submission that cross-references the DMF.

The open part of Type I DMFs may, therefore, be subject to discussions between the Therapeutic Products Directorate (TPD) and the submission sponsor for whom you have authorized Health Canada to access your DMF.

The closed part of Type I DMFs and all parts of Types II, III and IV DMFs will be kept confidential.

If any comments are considered necessary concerning the closed part of Type I DMFs or all parts of Types II, III and IV DMFs, they will be forwarded directly to the DMF Owner. In this case, the submission sponsor may be notified that there are outstanding issues that must be addressed before the DMF can be considered to support their drug submission.

It is recommended that Drug Master Files be **updated** every two years in order to keep these files open and active. Any changes or additions to the Drug Master File should be forwarded to the DMF Administration Unit as soon as possible.

If you have further questions on the administration of the Drug Master Files, please e-mail dmf_enquiries@hc-sc.gc.ca.

Yours sincerely,

Tania-Elena Di Millo-Briganti

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DMF Administration Unit