DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-558/S-053 + 15 others

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Jeffrey Tucker, M.D.
Senior Director, Regulatory Affairs
P.O. Box 1000, UG2CD-48
North Wales, PA 19454-1099

Dear Dr. Tucker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received March 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Supplement	Product
19-558	S-053	Prinivil® (lisinopril) Tablets, 5 mg, 10 mg, 20 mg
20-386	S-053	Cozaar® (losartan potassium) Tablets, 25 mg, 50 mg, 100 mg
20-685	S-072	Crixivan® (indinavir sulfate) Capsules, 100 mg, 200 mg, 400 mg
20-387	S-050	Hyzaar® (losartan potassium-hydrochlorothiazide) Tablets, 50-12.5 mg, 100-12.5 mg, 100-25 mg
22-145	S-015	Isentress® (raltegravir) Tablets, 400 mg
22-044	S-015	Janumet® (sitagliptin/metformin HCl) Tablets, 50/500 mg 50/1,000 mg
21-995	S-016	Januvia™ (sitagliptin) Tablets, 25 mg, 50 mg, 100 mg
19-643	S-082	Mevacor® (lovastatin) Tablets, 20 mg, 40 mg
19-384	S-055	Noroxin® (norfloxacin) Tablets, 400 mg
19-778	S-044	Prinzide® (lisinopril-hydrochlorothiazide) Tablets, 10-12.5 mg 20-12.5 mg
20-788	S-016	Propecia® (finasteride) Tablets, 1 mg
20-180	S-035	Proscar® (finasteride) Tablets, 5 mg
20-829	S-054	Singulair® (montelukast sodium) Tablets, 10 mg
20-830	S-055	Singulair® (montelukast sodium) Chewable Tablets, 4 mg, 5 mg
19-766	S-079	Zocor® (simvastatin) Tablets, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg
21-991	S-005	Zolinza® (vorinostat) Capsules, 100 mg

We acknowledge receipt of your amendments dated December 16, 2010, and March 2, 2011. The December 16, 2010, submissions constituted a complete response to our September 10, 2010, action letter.

These “Prior Approval” supplemental new drug applications provide for a standardized format for immediate container labels for the above referenced solid oral drug products.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter.

We acknowledge your amendment dated March 2, 2011, in which you indicated that you will cease the sampling of the Singulair brand by the end of 2011. Therefore, we agree with your proposal to deplete the currently approved inventory of physician sample carton labeling.

We remind you of your commitment made in the December 16, 2010, submission that following implementation of the new optimized packaging design, Merck will monitor the new design for three (3) years, will review any reports of medication errors related to the new design that are observed, and report them to the Agency on a quarterly basis.

Submit final printed immediate container labels, to each of their respective NDA, that are identical to the labels submitted on December 16, 2010, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” For administrative purposes, designate the submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA ##-###/S-###”** (use the appropriate NDA and supplement number listed in the table above). Approval of these submissions by FDA is not required before the labeling is used.

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 Michael Folkendt, Associate Director for Regulatory Affairs, at (301) 796-1670.

Sincerely,

{See appended electronic signature page}

Moheb M. Nasr
Director
Office of New Drug Quality Assessment
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MOHEB M NASR
06/10/2011