



ANDA 204354

**APPROVAL**

Mylan Pharmaceuticals, Inc.  
781 Chestnut Ridge Road  
PO Box 4310  
Morgantown, WV 26504-4310  
Attention: Joseph Sobecki  
Vice President, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 3, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Mesalamine Rectal Suppository, 1000 mg.

Reference is also made to the complete response letter issued by this office on May 1, 2014, and to your amendments dated March 9, July 30, and September 30, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Mesalamine Rectal Suppository, 1000 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Canasa Rectal Suppository, 1000 mg, of Forest Laboratories, LLC (Forest).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The “interim” dissolution specifications are as follows:

Medium	0.2 M Phosphate buffer, pH 7.5
Volume	900 mL
Apparatus	USP apparatus 2 (paddle)
Speed	125 rpm
Specification	NLT <sup>(b)</sup> <sub>(4)</sub> % (Q) of Mesalamine dissolved in 60 minutes

The “interim” dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the “interim” specifications or when the final specifications are tighter than the “interim” specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Forest's Canasa Rectal Suppository, 1000 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 8,217,083 (the '083 patent) and 8,436,051 (the '051 patent) are both scheduled to expire on June 6, 2028.

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Mesalamine Rectal Suppository, 1000 mg, under this ANDA. You have notified the agency that Mylan Pharmaceuticals, Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. The agency notes that these patents were submitted to the agency after submission of your ANDA and therefore, litigation if any, with respect to these patents creates no statutory stay of approval.

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Mesalamine Rectal Suppository, 1000 mg. Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Mesalamine Rectal Suppository, 1000 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the FD&C Act certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a “Post Approval Commitment Response.” To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as “POST APPROVAL COMMITMENT RESPONSE.”

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

**Carol A. Holquist -S**

Digitally signed by Carol A. Holquist -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,  
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Date: 2015.11.24 11:31:29 -05'00'

Carol A. Holquist, RPh  
Acting Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
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