



ANDA 215017

**ANDA APPROVAL**

MSN Pharmaceuticals Inc.  
U.S. Agent for MSN Laboratories Private Limited  
20 Duke Road  
Piscataway, NJ 08854-3714  
Attention: Kondal Reddy Bairy  
Associate Vice President

Dear Kondal Reddy Bairy:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 27, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Obeticholic Acid Tablets, 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on December 15, 2021, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Obeticholic Acid Tablets, 5 mg and 10 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ocaliva Tablets, 5 mg and 10 mg, of Intercept Pharmaceuticals, Inc. (Intercept).

The RLD upon which you have based your ANDA, Intercept's Ocaliva Tablets, 5 mg and 10 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
9,238,673 (the '673 patent)	June 17, 2033
10,047,117 (the '117 patent)	September 6, 2033
10,052,337 (the '337 patent)	April 26, 2036
10,174,073 (the '073 patent)	June 17, 2033
10,751,349 (the '349 patent)	April 26, 2036

10,758,549 (the '549 patent)      April 26, 2036

RE48,286 (the '286 patent)      February 21, 2027

Your ANDA contains paragraph IV certifications to each of the patents<sup>1</sup>, 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 Obeticholic Acid Tablets, 5 mg and 10 mg, under this ANDA. You have notified the Agency that MSN Laboratories Private Limited (MSN) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against MSN for infringement of the '673, '117, '337 and '073 patents in the United States District Court for the District of Delaware [Intercept Pharmaceuticals, Inc. and Intercept Pharma Europe Ltd. v. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., Civil Action No. 20-01105 (consolidated)]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that MSN was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Obeticholic Acid Tablets, 5 mg and 10 mg. Therefore, with this approval, MSN is eligible for 180 days of shared generic drug exclusivity for Obeticholic Acid Tablets, 5 mg and 10 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

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

## **REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> The Agency notes that the '349, '549 and '286 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.



Catherine  
Poole

Digitally signed by Catherine Poole

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