NDA 207356/S-004

SUPPLEMENT APPROVAL

Insmed Incorporated
Attention: Diane C. Fiorenza, BS
Vice President, Regulatory Affairs
700 U.S. Highway 202/206
Bridgewater, NJ 08807-1704

Dear Ms. Fiorenza:

Please refer to your supplemental new drug application (sNDA) dated and received February 27, 2020 and your amendments, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ARIKAYCE (amikacin liposome inhalation suspension), 590 mg.

We also refer to our letter dated January 30, 2020, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for ARIKAYCE. This information pertains to the risk of experiencing anaphylaxis and generalized hypersensitivity reactions.

This supplemental new drug application provides for revisions to the labeling for ARIKAYCE, consistent with our January 30, 2020 letter.

This information pertains to the risk of experiencing anaphylaxis and generalized hypersensitivity reactions and provides for revisions to the **HIGHLIGHTS**, **WARNINGS AND PRECAUTIONS (5)** section, **Anaphylaxis and Hypersensitivity Reactions (5.5)** subsection, the **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection and the **PATIENT COUNSELING INFORMATION (17)** section, of the prescribing information (PI). The **Medication Guide** was updated to be consistent with the PI. Minor editorial revisions were also made throughout the PI.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Fariba Izadi, PharmD, Safety Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, MD, MPH
Deputy Director for Safety
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOSEPH G TOERNER
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