U.S. FOOD & DRUG ADMINISTRATION

DATE: April 19, 2017

TO: MorphaBond (morphine sulfate) Extended-Release Tablets (NDA 206544) File

FROM: CDER Exclusivity Board

THROUGH: Sharon Hertz, MD, Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)

SUBJECT: Addendum to January 7, 2017, Memo re: Scope of 3-Year Exclusivity for MorphaBond

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This document is an addendum to a memorandum dated January 9, 2017, from the CDER Exclusivity Board (Board) regarding the Board's 3-year exclusivity recommendation for MorphaBond (morphine sulfate) extended-release tablets (NDA 206544) ("MorphaBond exclusivity memorandum"). This addendum seeks to clarify the scope of this exclusivity in light of the evolution of the Agency's approach to assessing 3-year exclusivity for certain AD opioids.

As set forth in the Board's January 9, 2017, memorandum, MorphaBond is the first FDA-approved, single-entity morphine product with a claim in the labeling related to deterring abuse via the intranasal route due to its physicochemical properties. Specifically, based on a HAL study which assessed the drug's abuse potential by the intranasal route of administration, MorphaBond was approved with labeling that describes certain properties of the product that are expected to reduce abuse by the intranasal route. Applying an approach to the scope of exclusivity in which the scope is defined by two primary characteristics: (1) the abuse route (intranasal); and (2) the type of abuse deterrence employed (physicochemical properties), the Board recommended that the scope of Morphabond's exclusivity be limited to the condition of approval supported by the intranasal HAL study, i.e., "labeling describing the expected reduction of abuse of a single-entity ER morphine by the intranasal route of administration due to physicochemical properties." FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) currently lists the following code for MorphaBond's exclusivity: "M-189: labeling describing the expected reduction of abuse of single-entity extended-release morphine by the intranasal route of administration due to physicochemical properties."

The Board has subsequently concluded that the extended-release aspect of MorphaBond was not a consideration in design of the intranasal HAL study, Study M-ARER-002, and thus was not relevant to determining the scope of exclusivity. Therefore, it is not part of the exclusivity-protected condition of approval supported by Study M-ARER-002. In general, HAL studies that assess deterrence of abuse through the *intranasal* route of administration do not take into account whether the proposed AD opioid product is an immediate-release or extended-release product. In other words, the design of the intranasal HAL studies does not depend on whether the

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proposed AD opioid is an immediate-release or extended-release product. Study M-ARER-002, an intranasal HAL study, did not evaluate the abuse potential of MorphaBond specifically with respect to its extended-release characteristics and therefore the extended-release aspect of MorphaBond is not part of the scope of its 3-year exclusivity. Rather, the scope of MorphaBond's exclusivity encompasses single-entity morphine products, regardless of drug release profile, that share the described conditions of approval.

The Board thus recommends that the scope of exclusivity for MorphaBond is labeling describing the expected reduction of abuse of single-entity morphine by the intranasal route of administration due to physicochemical properties. The Board recommends that the exclusivity code listed in the Orange Book be updated consistently with this recommendation and that the reference to MorphaBond's extended-release properties be removed from the code.

Sanjay Sitlani -S

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/s/

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04/20/2017