MOU Number: 225-19-014

MEMORANDUM OF UNDERSTANDING

BETWEEN

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

AND

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION

ARTICLE I. PARTIES

The Parties to this Memorandum of Understanding ("MOU") are the United States Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research ("CDER"), and the United States Consumer Product Safety Commission ("Commission"), Office of the Executive Director, Safety Operations.

ARTICLE II. PURPOSE

The purpose of this MOU is to set forth the terms and conditions under which the Parties may share information concerning household substances that are subject to the Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. § 1471-75, including specifically, household substances that require "special packaging," as defined by 15 U.S.C. § 1471(4), and that may also be "drugs" under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. § 321(g)(1)) ("CDER-regulated drugs"), and to promote timely communications between the Parties on issues related to such information.

ARTICLE III. AUTHORITIES

The authorities for entering into this MOU are as follows:

1. The FDA administers the FD&C Act (21 U.S.C. §§ 301 *et seq.*) and is responsible for promoting and protecting the public health by ensuring the safety and efficacy of drugs.

2. The CPSC administers the Consumer Product Safety Act ("CPSA") (15 U.S.C. § 2051 *et seq.*), and is responsible for protecting the public from unreasonable risks of injury or death associated with consumer products. The CPSC also administers the PPPA and is authorized to establish special packaging standards for household substances when "special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such

substance." 15 U.S.C. § 1472(a). The PPPA defines "household substance" to include "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household." 15 U.S.C. § 1471(2). The term "household substance" includes drugs as defined in the FD&C Act. *See* 15 U.S.C. § 1471(2)(B).

3. The CPSA, 15 U.S.C. § 2078(f), provides, in part, that notwithstanding the requirements of subsections (a)(3) and (b) of section 6 (15 U.S.C. § 2055), relating to public disclosure of information, the Commission may make information obtained by the Commission available to any federal, state, local, or foreign government agency, upon the prior certification of an appropriate official of any such agency, either by a prior agreement or memorandum of understanding with the Commission or by other written certification, that such material will be maintained in confidence and will be used only for official law enforcement or consumer protection purposes, if:

    a. The agency has set forth a bona fide legal basis for its authority to maintain the material in confidence;

    b. The materials are to be used for purposes of investigating, or engaging in enforcement proceedings related to, possible violations of --
        i. laws regulating the manufacture, importation, distribution, or sale of defective or unsafe consumer products, or other practices substantially similar to practices prohibited by any law administered by the Commission; or
        ii. a law administered by the Commission, if disclosure of the material would further a Commission investigation or enforcement proceeding.

4. The Parties agree to take actions under this MOU that are consistent with existing laws and regulations. Nothing in this MOU shall be construed as a change to current requirements under the statutes and regulations administered and enforced by FDA and CPSC. If a term of this MOU is inconsistent with such authority, then that term shall be invalid, but the remaining terms and conditions of this MOU shall remain in full force and effect. This MOU shall be interpreted and implemented in a manner that respects and complies with (and does not abrogate) the statutory and regulatory responsibilities of each party.

ARTICLE IV. INFORMATION TO BE EXCHANGED

A. Procedure Governing Information Exchanges

1. Authorized Officials and Contact Persons: The Director of CDER, or his or her designee, shall designate one or more Authorized Officials for CDER. The Office of the Executive Director, Safety Operations of the CPSC, shall appoint one or more Authorized Officials for CPSC. The Parties will exchange a list of Authorized Officials with each

other and will update such list whenever Authorized Officials change. The Authorized Officials shall also designate contact persons ("Authorized Contact Persons") to carry out the information exchanges outlined in section IV.B. The Parties will exchange a list of Authorized Contact Persons with each other and will update such list whenever Authorized Contact Persons change.

2. Timely Sharing of Information: The Parties will endeavor to exchange information covered by this MOU in a timely manner, but acknowledge that each may be limited by agency priorities, resources, and statutory or regulatory prohibitions.

3. Methods of Sharing Information: The Parties may share information in the following ways: in written form (including email) and verbally (including in-person meetings or by telephone, video-conferencing or other electronic means).

a. Written Exchanges of Information

When an Authorized Contact Person requests information, documents, or data, the request should be made in writing, which may include email. The following language should be included in the request:

> Information is being requested pursuant to 2019 CDER-CPSC Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or, if such disclosure is required by law, without advance notice to the originating agency.

By including this statement, requestors do not have to use a particular format or include other pre-specified text.

The response to such request should also be in written form. The following language should be included in any such response:

> This communication acknowledges that information is being shared pursuant to the 2019 CDER-CPSC Memorandum of Understanding. The information may not be further disclosed or shared in any manner without express written consent or, if such disclosure is required by law, without advance notice to the originating agency.

Additionally, each written document provided in response to a request shall be marked in the following manner:

CONFIDENTIAL/FOR OFFICIAL USE ONLY. Information shared by the Parties pursuant to 2019 CDER-CPSC Memorandum of Understanding. Further sharing or disclosure of this information with any other persons or entities is prohibited.

b. Exchanges of Information in Meetings and other Verbal Communications

The Parties may exchange information during meetings of the Parties (whether in person or by telephone, videoconference, or other electronic means). Meeting announcements

and agendas, distributed background information, or meeting minutes for such inter-agency meetings will include the following language:

> Information shared during this meeting will be/was pursuant to the 2019 CDER-CPSC Memorandum of Understanding. Such information may not be further disclosed or shared in any manner without the express written consent of the originating agency, or, if such disclosure is required by law, without advance notice to the originating agency.

4. Prohibited Exchange of Information Between the Parties: All information exchanges between the Parties must be made in accordance with existing laws, regulations, policies, and this MOU. Any information exchanges that are not made in accordance with existing laws, regulations, policies, and this MOU, are not permitted and are considered prohibited exchanges. Any prohibited information exchanges must still be safeguarded and protected, as discussed in Article V.A of this MOU. Each Party has an affirmative obligation to notify affected personnel of their responsibilities and obligations under this MOU to prevent prohibited exchanges.

5. Mitigation of Prohibited Exchanges: The undersigned agree that certain non-public information (directly or indirectly (*i.e.*, through verbal or written communication, conduct or any other means)) that is not disclosed in accordance with applicable laws, regulations, policies, and this MOU may be detrimental to agency activities and may interfere with the Parties' ability to protect personal privacy, confidential and/or trade secret information. Accordingly, if a Party becomes aware of a prohibited exchange, it will immediately notify an Authorized Official of the other Party, providing the content of the prohibited exchange or disclosure, the identity of the person by whom it was made, the identity of the person to whom it was made, and the date on which the prohibited exchange occurred. The Parties will work with one another to develop and implement a plan to remedy the prohibited exchange or disclosure, taking into consideration the Parties' responsibility to preserve documents and records in accordance with applicable law or legal process.

B. Substance of Information to Be Exchanged Under this MOU

1. Information to Be Shared by CPSC to CDER: CPSC will notify CDER regarding any special packaging activity that relates to, and/or affects, any CDER-regulated drug by emailing CDEREXSEC@cder.fda.gov and such other Authorized Contact Person.

In particular, CPSC will notify CDER in the manner described for the following situations:

a. CPSC Development of a Special Packaging Rule

When a majority of the Commission votes to approve staff resources to develop a special packaging rule that may impact a CDER-regulated drug, CPSC will notify CDEREXSEC@cder.fda.gov and such other Authorized Contact Person.

b. When CPSC Issues a Notice of Non-Compliance or When CPSC Identifies a Potential Compliance Issue for CDER

When CPSC confirms a special packaging violation by issuing a "Notice of Non-Compliance," also known as a "Letter of Advice" ("LOA") that affects a CDER-regulated drug, CPSC will notify CDEREXSEC@cder.fda.gov and such other Authorized Contact Person at the earliest feasible time with a copy of the LOA. CPSC may also notify CDEREXSEC@cder.fda.gov and such other Authorized Contact Person if it identifies a potential compliance issue that affects a CDER-regulated drug.

c. When CPSC Plans to Announce a Recall

When CPSC plans to announce a recall related to special packaging that affects a CDER-regulated drug, CPSC will notify CDEREXSEC@cder.fda.gov and such other Authorized Contact Person at the earliest feasible time and prior to the public announcement of the recall.

2. Information to Be Shared by CDER to CPSC: CDER will notify ICDO_OEX@cpsc.gov and such other Authorized Contact Person regarding CDER activity that relates to, and/or affects, special packaging.

In particular, CDER will notify CPSC in the manner described for the following situations:

a. Semi-Annual Adverse Events Summary Reports

Semiannually, CDER will provide CPSC with a summary report of incidents from the FDA Adverse Events Reporting System ("FAERS") concerning CDER-regulated drugs that may involve special packaging violations or compliance issues by emailing ICDO_OEX@cpsc.gov and such other Authorized Contact Person. When CPSC requires individual reports from the FAERS summary report, CPSC will email its request to: CDEREXSEC@cder.fda.gov and such other Authorized Contact Person and CDER will provide the requested information at the earliest feasible time.

b. Other Adverse Events Reports

When CPSC requires other FAERS data, CPSC will email its request to CDEREXSEC@cder.fda.gov and such other Authorized Contact Person and CDER will provide the requested information at the earliest feasible time.

c. When CDER Finds Potential Compliance Issues with Special Packaging

CDER does not assess whether the packaging of CDER-regulated drugs complies with CPSC's special packaging requirements. However, if CDER discovers that the packaging for a CDER-regulated drug may not comply with CPSC's special packaging

requirements, CDER may notify ICDO_OEX@cpsc.gov and such other Authorized Contact Person at the earliest feasible time.

d. When CDER Changes a Drug's Status from Prescription to Nonprescription

When CDER has determined that an original prescription product no longer meets the criteria in section 503(b)(1) of the FD&C Act (21 U.S.C. § 353(b)(1)) for prescription use and the drug's status changes from prescription to nonprescription (commonly referred to as an "Rx to OTC switch"), CDER will notify ICDO_OEX@cpsc.gov and such other Authorized Contact Person at the earliest feasible time.

Following notification for any of the above, CDER and CPSC will consult, as needed.

ARTICLE V. GENERAL PROVISIONS

A. Safeguarding & Limiting Access to Shared Information

The undersigned recognize that information exchanged that contains any of the following types of information must be protected from unauthorized use and disclosure:

(1) information that will permit the public to ascertain readily the identity of a manufacturer or private labeler of a consumer product protected from public disclosure pursuant to 15 U.S.C. § 2055;

(2) information specifically exempted from disclosure by statute pursuant to Exemption 3 of the Freedom of Information Act (FOIA), including, but not limited to, information covered by 15 U.S.C. § 2055;

(3) confidential commercial information, such as information that would be protected from public disclosure pursuant to Exemption 4 of the FOIA, 5 U.S.C. § 552(b)(4);

(4) personal privacy information, such as information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA, 5 U.S.C. § 552(b)(6), (b)(7)(C);

(5) information compiled for law enforcement purposes, such as information that would be protected from public disclosure pursuant to Exemption 7 of the FOIA, § 552(b)(7)(E); or

(6) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(b)), the Consumer Product Safety Act, 15 U.S.C. § 2051 *et seq.*, the Federal Food, Drug, and Cosmetic

Act (21 USC 301 *et seq.*), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

The Parties will ensure that information shared under this MOU shall be used and disclosed solely in accordance with applicable laws, regulations, and policies. Access to the information shared under this MOU shall be restricted to authorized employees and officials of the Parties who require access to perform their official duties in accordance with the use of information as authorized by this MOU. Such personnel shall be advised of (1) the necessity to safeguard and limit access to the information, and (2) the administrative, civil, and criminal penalties for noncompliance contained in applicable federal laws.

If either Party receives a Freedom of Information Act ("FOIA") request for information provided by the other Party pursuant to this MOU, the Party receiving the FOIA request will refer the request to the Party that provided the information to respond directly to the requestor. The Party that refers the request will notify the requestor that a referral has been made to the other Party and that a response will issue directly from the other Party. In such cases where a Party has incorporated another Party's information in a responsive record, the Party should consult with the Party whose information appears in the responsive records.

Nothing in this MOU shall be construed to prevent a disclosure required by law or legal process. Notwithstanding this provision, should information shared pursuant to this MOU be subpoenaed or otherwise ordered through a legal process, the Party to whom the subpoena or order is directed will immediately notify an Authorized Official of the other Party to provide an opportunity to seek to intervene and prevent the disclosure.

Termination of this MOU does not relieve either of the Parties of their obligation to safeguard, protect, and limit access to the shared information established under section IV of this MOU.

ARTICLE VI. WAIVER AND AMENDMENT

The requirements of this MOU may be waived or amended only by the mutual written agreement of the Director of CDER and the CPSC's Deputy Executive Director of Safety Operations in a specific circumstance, but neither Party may waive requirements or restrictions imposed by federal law. The Parties' failure to enforce or abide by any requirement of this MOU, whether once or repeatedly, is not to be construed as a waiver of the requirement and cannot be deemed to alter or amend the MOU.

VII. TERM, TERMINATION AND MODIFICATION

This MOU, when accepted by the undersigned, will become effective from the date of the latest signature and re-evaluated 1 year from the date of execution and then every two years thereafter. This MOU will continue in effect, unless modified or terminated by

mutual written consent by both Parties, or may be terminated by either Party upon a 30-day advance written notice to the other.

Approved for the
Consumer Product Safety Commission

By: DeWane Ray
Deputy Executive Director
Safety Operations

DEWANE RAY
Print Name

5/28/19
Date

Approved for the
Food and Drug Administration

By: Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Janet Woodcock
Print Name

6/13/19
Date