IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. CROWN LABORATORIES, INC., a corporation and JEFFERY BEDARD, an individual, Defendants.	Civil Action No.: 2:17-cv-36 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. §§ 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. Introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce, manufacturing, processing, packaging, labeling, holding, or selling any Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), or any drug labeled similarly to such drugs and containing the same active ingredient(s), unless and until an approved new drug application or an abbreviated new drug application or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs;

B. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is a new drug within the meaning of 21 U.S.C. § 321(p) and that is neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under to 21 U.S.C. § 355(i);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

D. Violating of 21 U.S.C. § 331(k) by, directly or indirectly, causing any drug that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Directly or indirectly causing to be done any act that results in the failure to implement and continuously maintain the requirements of this Decree.

Nothing in this paragraph or paragraph 7 or paragraph 9 shall preclude Defendants from marketing a drug subject to an ongoing Drug Efficacy Study Implementation (DESI) proceeding during the pendency of that proceeding. The preceding sentence does not apply when a DESI proceeding closes. No provision of this Decree shall affect the authority of the United States to bring an action against Defendants for a violation of the Act and/or its implementing regulations.

7. A. Within twenty (20) business days after entry of this Decree, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy all Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide, any unapproved drug labeled similarly to such drugs and containing the same active ingredient(s), and any unapproved new drugs not expressly listed herein, in Defendants' custody, control, or possession (hereinafter, "Violative Drugs"). Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction.

B. Defendants shall at all times, until all of the Violative Drugs have been destroyed in accordance with this Decree, retain the Violative Drugs intact for examination or inspection by FDA at their facility at 349 Lafe Cox Drive, Johnson City, Tennessee ("the Facility"), and shall maintain all records or other proof necessary to establish the identity of the Violative Drugs to FDA's satisfaction. Defendants shall not cause the Violative Drugs to be

disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed.

C. Within fifteen (15) business days after receiving authorization from FDA to commence destroying the Violative Drugs, Defendants shall, under FDA supervision, complete the destruction in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in Paragraph 13, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

8. FDA shall be permitted, without prior notice and as FDA deems necessary, to make inspections of Defendants' place(s) of business (including, but not limited to, the Facility) and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate

corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all unapproved or misbranded drugs;

B. Recall, at Defendants' expense, any drugs that are unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; or

F. Take any other corrective actions with respect to unapproved or misbranded drugs as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

10. Any order issued by FDA pursuant to Paragraph 9 shall be issued by the appropriate FDA District Director, and shall specify the deficiencies or violations giving rise to the order. Unless a different time frame is specified by FDA in its order, within five (5) business days after receiving an order pursuant to Paragraph 9, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking, or have undertaken, the specified corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and a proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

A. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

B. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order unless the Court stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this subparagraph shall be made in accordance with the terms set forth in Paragraph 19.

C. The process and procedures set forth in Paragraph 10.A-B shall not apply to any order issued under Paragraph 9 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while implementing the order.

11. Any action ordered pursuant to Paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 9 shall be borne by Defendants at the rates specified in Paragraph 13.

12. The prohibitions set forth in Paragraphs 6 and 7 or in any order issued under Paragraph 9 shall not apply to any drug manufactured solely for export and/or exported from the United States, provided that all applicable requirements of the Act, including 21 U.S.C. §§ 381(e) and 382, and its implementing regulations have been satisfied with respect to such drug.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $90.65 per hour or fraction thereof per representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Facility, at any other location at which Defendants conduct business, and on Crown Laboratories, Inc.'s website, and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

15. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (hereafter collectively referred to as "Associated Persons"). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any Defendant becomes associated

with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Crown Laboratories, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

19. All decisions specified in this Decree shall be vested in FDA's discretion and shall be final. If contested by Defendants, FDA's decisions under this Decree shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the case name and civil action number, be prominently marked "Decree Correspondence" and "Crown Laboratories, Inc." and be addressed to:

District Director
New Orleans District Office
U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2565

21. Should Defendants fail to comply with any provision of this Decree, then they shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues, an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation of this Decree, and an additional sum equal to three (3) times the retail value of each shipment of an unapproved new drug and/or a misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017.

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

For Plaintiff

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Individually and on behalf of
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/s/

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24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

JEFFERY BEDARD
Individually and on behalf of
Crown Laboratories, Inc.

For Plaintiff

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