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.: _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Crown Laboratories, Inc. ("Crown" or "the firm") is a corporation incorporated and registered to do business in Tennessee. Crown operates at its principal place of business and drug manufacturing facility, which is located at 349 Lafe Cox Drive, Johnson City, Tennessee (the "Facility"), within the jurisdiction of this Court.

5. Crown manufactures, processes, packs, labels, holds, and distributes a variety of prescription and over-the-counter ("OTC") drugs including, but not limited to, prescription urea cream and lotion, and prescription Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), which are the subject of this action. Specifically, Crown manufactures, processes, packs, labels, holds, and distributes in interstate commerce Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) under its own labels. Crown also manufactures, processes, packs, labels, holds, and distributes in interstate commerce Sodium Sulfacetamide as a contract manufacturer for another pharmaceutical firm.

6. Defendant Jeffery Bedard is Crown's Chief Executive Officer. He is responsible for, and has authority over, all operations at the firm. He has the authority and duty to prevent, detect, and correct objectionable conditions. He performs his duties at the Facility, within the jurisdiction of this Court.

DEFENDANTS' VIOLATIONS OF THE ACT

Unapproved New Drugs

7. A product is a drug within the meaning of the Act, inter alia, if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

8. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

9. The products Defendants introduce or deliver for introduction into interstate commerce are drugs within the meaning of the Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and/or intended to affect the structure or any function of the body of man. Specifically, according to the products' labels, Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) are intended to treat hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratosis, and calluses, and Sodium Sulfacetamide is intended to treat acne vulgaris, acne rosacea, and seborrheic dermatitis.

10. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or any drug . . . the

composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p).

11. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver, or cause to be introduced or delivered, into interstate commerce a new drug that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

12. Defendants' 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), and Sodium Sulfacetamide are "new drugs" within the meaning of the Act, inter alia, because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. § 321(p)(1).

13. There is no application under 21 U.S.C. § 355 on file with FDA for 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), or Sodium Sulfacetamide that would allow Crown to introduce or deliver these products, or cause them to be introduced or delivered, into interstate commerce to the public.

14. Defendants' introduction or delivery for introduction of these drug products into interstate commerce therefore violates 21 U.S.C. § 331(d).

Misbranded Drugs

15. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

16. A drug is misbranded if its labeling fails to bear "adequate directions for use," and does not fall within a regulatory exemption from this requirement. 21 U.S.C. § 352(f)(1); 21 C.F.R. Part 201, Subpart D.

17. Defendants' 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), and Sodium Sulfacetamide are prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(B). The labeling of these products state that they are intended for "Rx Only" use.

18. Defendants' 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), and Sodium Sulfacetamide are misbranded because they do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.100 or 201.115. A new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its approved application. See 21 C.F.R. § 201.115. Moreover, a prescription drug that is a new drug can qualify for the exemption from the adequate directions for use requirement if its labeling bears the information authorized by an approved new drug application. See 21 C.F.R. § 201.100(c)(2). New drugs that lack an approved NDA, such as Defendants' prescription drugs, cannot qualify for either of these exemptions and therefore are misbranded as a matter of law.

19. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

20. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug, as defined by 21 U.S.C. § 321(g)(1), to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Interstate Commerce

21. During the most recent inspection of the Facility between February 22 and 25, 2016, FDA documented Defendants' shipment of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion to Georgia and Utah, and of Dermasorb XM Trade Kit (Urea 39% Cream and Moisturizer) to California. FDA also documented Defendants' shipment of Sodium Sulfacetamide to Ohio. These shipments constitute the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. §§ 331(a) and (d).

22. Defendants receive raw materials from outside of Tennessee, which they use to manufacture their drug products. For example, Defendants receive the active pharmaceutical ingredients Urea USP from Ohio and Sodium Sulfacetamide Monohydrate from Mississippi. Therefore, the interstate commerce element under 21 U.S.C. § 331(k) is met.

HISTORY

23. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

24. During a meeting with Defendants on December 2, 2015, FDA notified

Defendants that unapproved, marketed drugs are not listed in the FDA Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, (35th ed. 2015), which is a compilation of drugs approved by FDA on the basis of safety and effectiveness whose applications have not been withdrawn or suspended for safety or effectiveness reasons and FDA's evaluations on the therapeutic equivalence of drugs, and that the marketing of these products absent an approved application may violate the Act and subject them compliance action.

25. During an inspection of the Facility between March 2 and 3, 2015, FDA documented Defendants' distribution in interstate commerce of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion. By letter dated May 13, 2015, FDA explained to then counsel for Defendant Crown that 40% Urea Cream, 40% Urea Lotion, 39% Urea Lotion, and Sodium Sulfacetamide are new drugs that are subject to the Act's premarket approval requirement.

26. During an inspection of the Facility between February 10 and 14, 2014, FDA documented, among other things, Defendants' manufacturing and distribution in interstate commerce of prescription urea drugs privately labeled for Ascend Laboratories, LLC (hereafter, "Ascend"), specifically products labeled as Ascend Urea Cream 40% and Ascend Urea 40% Lotion. FDA also documented Defendants' manufacturing and distribution in interstate commerce of Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) and Sodium Sulfacetamide during the inspection. The FDA investigator discussed the potential unapproved status of these drugs with firm management, including Defendant Bedard, and made them aware of FDA's Compliance Policy Guide Section 440.100, Marketed New Drugs Without Approved NDAs or ANDAs, amended September 19, 2011 ("CPG Section 440.100"); see also 76 Fed. Reg. 58398-01 (Sept. 21, 2011). In CPG Section 440.100, FDA notified manufacturers and

distributors that any product that is being illegally marketed is subject to enforcement at any time and that all unapproved drugs introduced onto the market after September 19, 2011, are subject to immediate enforcement action without prior notice and without respect to the enforcement priorities listed therein. See also 76 Fed. Reg. at 58399.

27. In May 2014, the United States conducted a seizure of certain unapproved and misbranded drugs that were being distributed by Ascend, including but not limited to the urea drug products that Defendants had manufactured for Ascend (Ascend Cream Urea 40% Cream, Ascend Urea Lotion 40%, and Ascend Urea Cream 39%). The United States notified Defendants of the seizure by letter dated May 15, 2014.

28. Defendant Bedard stated, by letter dated March 5, 2014 to FDA, that Crown "does not currently plan to file an NDA for any of these products . . . ." During FDA's February 2016 inspection, the firm's Vice President of Quality Assurance and Quality Control, stated that he believes that the products at issue are legal drug products and that they will continue to be manufactured and shipped in the future.

29. Accordingly, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (d), and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drug, including but not limited to 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), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredients, unless and until an approved new drug application, 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.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, 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), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredient(s) in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect Defendants' place(s) of business and all

records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 1st day of March, 2017.

Respectfully submitted,

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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.: _____ 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 ___ day of _____ 2017.

_____

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

_____

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

For Plaintiff

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

MICHAEL S. BLUME
Director
Consumer Protection Branch

___/s/_____

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., Suite 6400 South
Washington, DC 20001
Telephone: 202-307-0088
Fax: 202-514-8742
Megan.Englehart@usdoj.gov

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.

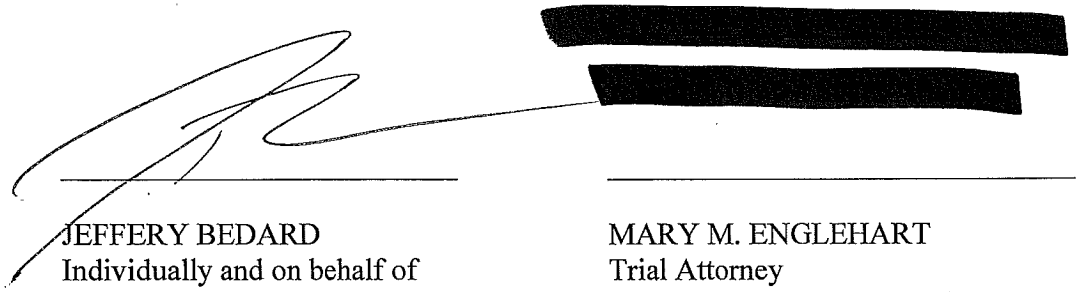
Dated this ___ day of _____ 2016.

_____

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants



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

For Plaintiff

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
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450 Fifth Street, N.W., Suite 6400 South
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Megan.Englehart@usdoj.gov

Daniel G. Jarcho
Attorney for Jeffery Bedard

Daniel G. Jarcho
Attorney for Crown Laboratories, Inc.

OF COUNSEL:

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U.S. Dept. of Health & Human Services

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Food and Drug Division

ANNAMARIE KEMPIC
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Food and Drug Division

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301-348-3010

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Attorney for Jeffery Bedard

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OF COUNSEL:

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301-348-3010

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Mary M. Englehart, Trial Attorney, Consumer Protection Branch, USDOJ
450 5th Street, NW, Washington, DC 20001 Tel: 202-307-0088

DEFENDANTS

Crown Laboratories, Inc.

County of Residence of First Listed Defendant Washington County, TN
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

Daniel G. Jarcho, Alton & Bird, LLP
950 F Street, NW, Washington, DC 20004-1404

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
21 U.S.C. Section 332

Brief description of cause:
Injunction Proceeding under the Federal Food Drug and Cosmetic Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
03/01/2017

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____