

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

v.

DR. REDDY'S LABORATORIES, INC.,

Defendant.

Civil Action No. 17-13219

CONSENT DECREE OF CIVIL PENALTY AND PERMANENT INJUNCTION

Plaintiff, the United States of America, has commenced this action by filing a Complaint pursuant to 15 U.S.C. §§ 2068, 2069, and 2071(a) alleging violations of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2051 et seq., against Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"). Dr. Reddy's has waived service of the summons and the complaint.

The parties, represented by the counsel identified below, have agreed to this settlement of the action without adjudication of any issue of fact or law and consent to the entry of this Consent Decree of Civil Penalty and Permanent Injunction ("Decree"). THEREFORE, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

1. In its Complaint, the United States alleges Dr. Reddy's knowingly violated 15 U.S.C. § 2068(a)(1) by selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States household oral prescription drugs that were not in conformity with a consumer product safety rule or similar rule, regulation, standard, or ban under an Act enforced by the Commission, namely, the Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. § 1471-77.

2. The Complaint also alleges that Dr. Reddy's knowingly violated 15 U.S.C. § 2068(a)(4) by failing to immediately furnish to the Consumer Product Safety Commission

(“CPSC” or “Commission”) the information required by 15 U.S.C. § 2064(b). The Complaint alleges that Dr. Reddy’s obtained information that reasonably supported the conclusion that household oral prescription drugs packaged in non-child resistant blister packs that Dr. Reddy’s imported and distributed (1) failed to comply with any rule, regulation, standard, or ban under the CPSA or any Act enforced by the Commission, namely, the PPPA; (2) contained a defect which could create a substantial product hazard; and (3) created an unreasonable risk of serious injury or death.

3. The Complaint further alleges that Dr. Reddy’s knowingly violated 15 U.S.C. § 2068(a)(6) by failing to comply with the general conformity certification requirements of 15 U.S.C. § 2063(a), which requires a certification based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or an Act enforced by the Commission, namely, the PPPA.

4. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1345, 1355(a) and 15 U.S.C. §§ 2069(a), 2071(a). Venue in this district is proper under 28 U.S.C. §§ 1391(b), (c) and 1395(a).

5. The Complaint states a claim upon which relief may be granted under the Consumer Product Safety Act, 15 U.S.C. §§ 2068(a), 2069(a), 2071(a).

6. Dr. Reddy’s enters into this Decree freely and without coercion. Dr. Reddy’s further acknowledges that it has read the provisions of this Decree and is prepared and able to abide by them.

7. The United States believes settlement of this case on the terms described below is in the public interest and that injunctive relief is necessary to prevent future violations of the CPSA.

8. Dr. Reddy’s does not admit that the law has been violated and believes settlement is appropriate to avoid the time and expense of litigation.

9. Dr. Reddy's admits that this Court has personal and subject-matter jurisdiction of this matter, and that venue in this district is proper.

10. Dr. Reddy's waives any claim that it may hold under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date this Decree is entered by the Court. All parties agree to bear their own fees, costs, and attorney's fees.

CIVIL PENALTY

11. Dr. Reddy's shall pay five million dollars (\$5,000,000) to the United States as a civil penalty pursuant to 15 U.S.C. § 2069. Within fourteen (14) calendar days after entry of this Decree, Dr. Reddy's will pay the civil penalty payment in the form of an electronic fund transfer in accordance with the procedures specified by the Consumer Protection Branch, Civil Division, U.S. Department of Justice, Washington, DC 20530.

12. In the event of any default in payment required in Paragraph 11, the entire unpaid amount shall constitute a debt due and immediately owing by Dr. Reddy's to the United States, and interest shall accrue and be paid by Dr. Reddy's at the federal legal rate of interest set forth at 28 U.S.C. § 1961 from the date of default until the payment has been paid in full.

13. Dr. Reddy's relinquishes all dominion, control, and title to the funds paid to the fullest extent permitted by law. Dr. Reddy's shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise.

14. The judgment amount set forth in this Section represents a civil penalty owed to the United States Government, is not compensation for actual pecuniary loss, and, therefore, is not subject to discharge under the Bankruptcy Code pursuant to 11 U.S.C. § 523(a)(7).

INJUNCTIVE RELIEF

15. Dr. Reddy's shall comply with the PPPA, 15 U.S.C. § 1471–77, and sections 19(a)(1), 19(a)(4), and 19(a)(6) of the CPSA, 15 U.S.C. §§ 2068(a)(1), (a)(4), and (a)(6), with respect to any

household oral prescription drug product imported, manufactured, distributed, or sold by Dr. Reddy's that requires special packaging under 16 C.F.R. § 1700.14.

16. Dr. Reddy's shall implement and shall maintain a compliance program designed to ensure compliance with the PPPA and CPSA that, at a minimum, contains the following elements:

a. written standards, policies, and procedures including those designed to ensure that information that may relate to or impact PPPA or CPSA compliance is conveyed effectively to personnel responsible for such compliance;

b. a mechanism for confidential employee reporting of PPPA or CPSA compliance-related questions or concerns to either a compliance officer or to another senior manager with authority to act as necessary;

c. procedures that provide for the appropriate forwarding to CPSC Office of Compliance personnel of all information, that is not otherwise protected by the attorney-client privilege or the attorney work product and described in a privilege log provided to CPSC Office of Compliance personnel, that may relate to, or impact, PPPA or CPSA compliance, including but not limited to information relating to the packaging of oral prescription drugs, whether an injury is referenced or not;

d. procedures for reviewing claims and reports for PPPA or CPSA compliance concerns and for implementing corrective and preventive actions when PPPA or CPSA compliance deficiencies or violations are identified;

e. effective communication of company compliance-related policies and procedures regarding the PPPA and the CPSA to all applicable employees through training programs or otherwise;

f. senior management responsibility for compliance and accountability for violations of the PPPA and the CPSA;

g. oversight of PPPA and CPSA compliance by a Dr. Reddy's governing body;
and

h. retention of all records reasonably related to compliance with the PPPA and the CPSA for at least five (5) years and availability of such records to CPSC staff upon request.

17. With respect to any household oral prescription drug product imported, manufactured distributed or sold by Dr. Reddy's that requires special packaging under 16 C.F.R. § 1700.14, Dr. Reddy's shall maintain and enforce a system of internal controls and procedures designed to ensure that:

a. information required by law to be disclosed by Dr. Reddy's to the CPSC is recorded, processed, and reported in accordance with applicable law;

b. all reporting made to the CPSC is timely, truthful, complete, and accurate;
and

c. prompt disclosure is made to Dr. Reddy's management of any material deficiencies or material weaknesses in the design or operation of such internal controls that are reasonably likely to adversely affect in any material respect Dr. Reddy's ability to record, process, and report to the CPSC in accordance with applicable law.

18. Upon reasonable request of CPSC staff, Dr. Reddy's shall cooperate fully and truthfully with CPSC staff and shall make available all information, materials, and personnel reasonably necessary for CPSC staff to evaluate Dr. Reddy's compliance with the terms of this Decree, subject to applicable privileges, and with provisions for maintaining the confidentiality of confidential information in accordance with 15 U.S.C. § 2055.

MISCELLANEOUS PROVISIONS

19. Dr. Reddy's shall ensure compliance with this Decree by providing a copy of this Decree to all employees with direct oversight and/or responsibility for compliance with the PPPA

and the CPSA and require those employees to certify in writing that they have read this Decree.

20. This Decree shall be binding on the successors and assigns of Dr. Reddy's, and any such successors and assigns shall be subject to the terms of this Decree.

21. For a period of five (5) years from the entry of this Decree by the Court, Dr. Reddy's shall notify the CPSC General Counsel in writing within thirty (30) calendar days after any reorganization, consolidation, merger, acquisition, dissolution, assignment, sale, transfer, or similar transaction or series of transactions resulting in a successor entity to Dr. Reddy's, the transfer or disposition of substantially all of the assets of Dr. Reddy's, or any other changes in corporate structure that Dr. Reddy's determines in good faith may affect compliance obligations arising out of this Decree.

22. Dr. Reddy's shall notify the CPSC General Counsel in writing within fourteen (14) calendar days after any change in the person to which communications from the CPSC should be addressed.

23. The provisions of this Decree are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in full force and effect.

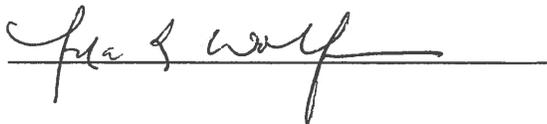
24. This Court retains jurisdiction of this matter for the purpose of enabling any of the parties to this Decree to apply to the Court at any time for such further orders or directives as may be necessary or appropriate for the enforcement of compliance therewith, or for the punishment of violations thereof.

25. The United States shall be reimbursed by Dr. Reddy's for reasonable costs and attorneys' fees upon succeeding in a suit to enforce this Decree.

26. The parties, by their respective counsel, hereby consent to entry of the foregoing Decree, which shall constitute a final judgment and Order in this matter. The parties further

stipulate and agree that the entry of the foregoing Decree shall constitute full, complete, and final settlement of this action.

SO ORDERED this 18th day of January, ²⁰¹⁸~~2017~~.

A handwritten signature in cursive script, appearing to read "Paul S. Wolf", is written over a horizontal line.

United States District Judge

FOR THE UNITED STATES:

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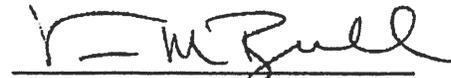
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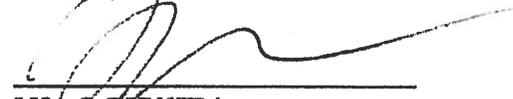
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