## State of California - Department of Justice - Attorney General's Office - Proposition 65 Enforcement Reporting

FORM JUS 1502 (03-01) Attention: Prop 65 Coordinator, 1515 Clay Street, Suite 2000, Oakland, CA 94612

PRIVATE ENFORCEMENT FILING - Health and Safety Code section 25249.7(e) and (f)

## REPORT OF ENTRY OF JUDGMENT

Please	print or type required information	Original Filing	O Supplemental Fili	ng Corrected Filing	
PARTIES TO THE ACTION	PLAINTIFF(S) Shefa LMV Inc.  DEFENDANT(S) INVOLVED IN JUDGMENT Janssen Pharmaceut:	icals, Inc			
CASE INFO	COURT DOCKET NUMBER JCCP004765  SHORT CASE NAME Proposition 65 Cocamide DEA Cases			RTNAME ameda County Su	perior Court
REPORT INFO	INJUNCTIVE RELIEF Reformulation  PAYMENT: CIVIL PENALTY \$12,000.00  DATE SUBMITTED TO COURT  06 /12 /2017	PAYMENT: ATTORN \$38,000.0 IS JUDGMENT PURE TO SETTLEMENT?  Yes	NEYS FEES PAOD 0	YES, DATE SETTLEMENT WAS EPORTED TO ATTORNEY GENER/	For Internal Use Only
FILER	NAME OF CONTACT Daniel N. Greenbaum ORGANIZATION Law Office of Danie ADDRESS 7120 Hayvenhurst Av CITY Van Nuys	el Greenba	320	MAIL ADDRESS greenbaum@green	TELEPHONE NUMBER ( 818 ) 809-2199  FAXNUMBER ( 424 ) 243-7689  baumlawfirm.com

**FILING INSTRUCTIONS:** This form can be completed online and printed. If electronic filing is not available, mail the completed form with a copy of the judgment to the attention of the Prop 65 Coordinator at the address shown above. If you need additional space to complete this form please use an attachment.



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11	_					
12	Attorneys for Defendant JANSSEN PHARMACEUTICALS, INC.					
13	SUPERIOR COURT OF THE STATE OF CALIFORNIA					
14	FOR THE COUNTY OF ALAMEDA					
	TOK THE COOK!					
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16	Coordination Proceeding	) JUDICIAL COUNCIL COORDINATION				
10	Special Title (Rule 3.350)	) PROCEEDING NO: 4765				
17		)				
		) [Shefa LMV, LLC v. Target Corp., et al., Los				
18	THE STREET STREET	) Angeles County Superior Court No.				
19	PROPOSITION 65 COCAMIDE DEA	) BC520410]				
19	CASES					
20		) [PROPOSED] CONSENT JUDGMENT AS				
		) TO JANSSEN PHARMACEUTICALS, ) INC.				
21		Y INC.				
22		Judge: Hon. George C. Hernandez, Jr.				
		Action filed: September 4, 2013				
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-"	[PROPOSED] CON	SENT JUDGMENT				
		JTICALS, INC JCCP No. 4765				

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# 1. INTRODUCTION

- 1.1 Parties. The parties to this consent judgment ("Consent Judgment") are Shefa LMV, LLC ("Shefa" or "Plaintiff") and JANSSEN PHARMACEUTICALS, INC. ("Settling Defendant"). Shefa and Settling Defendant are referred to collectively as the "Parties" or, singularly, as a "Party."
- 1.2 **Products.** The Settling Defendant manufactures, distributes, and/or sells types of products identified on Exhibit A. Plaintiff alleges that the Covered Products sold by Settling Defendant in the State of California, or sold in the past by Settling Defendant in the State of California, contain or contained cocamide diethanolamine ("Cocamide DEA") at levels requiring a warning under California's Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code §§ 25249.5, et seq. ("Proposition 65"). Settling Defendant denies Plaintiff's allegations.
- 1.3 Notice of Violation. On February 24, 2015, Shefa served 60-Day Notices ("Notices") of Violation under Proposition 65 to Settling Defendant, the California Attorney General, the District Attorneys of every County in the State of California, and the City Attorneys for every City in the State of California with a population greater than 750,000. The Notices allege violations of Proposition 65 with respect to the presence of Cocamide DEA in the types of products identified in Exhibit A. If one or more additional Notices would be necessary for all the Covered Products to be included in this Consent Judgment, Plaintiff shall timely issue such Notices sufficiently in advance of any motion to approve this Consent Judgment so that the sixty-day notice period, plus any additional time period for service of such Notices, shall have elapsed prior to the initial date set for the Court's hearing such motion to approve this Consent Judgment.
- 1.4 **Complaint.** On April 17, 2015, Shefa filed the Complaint applicable to the Settling Defendant ("Complaint") for the Proposition 65 Action identified in Section 4 of Exhibit A.
- 1.5 Jurisdiction. For purposes of this Consent Judgment only, the Parties stipulate that: (i) this Court has jurisdiction over the allegations of violations contained in the operative Complaint applicable to Settling Defendant and personal jurisdiction over Settling Defendant as

to the acts alleged in the Complaint; (ii) venue is proper in the County of Alameda; and (iii) this Court has jurisdiction to enter this Consent Judgment. The Parties recognize that the Covered Products are prescription-only products and, as such, are governed by specific regulatory requirements imposed by the United States Food, Drug, and Cosmetics Act, 21 United States Code Section 301 et seq. Additionally, the Covered Products are governed by additional regulatory requirements, including without limitation regulations issued by the European Union. By agreeing to the jurisdiction of the Court in this action, Settling Defendant does not: (a) concede that the application of Proposition 65 to the Covered Products is not preempted by federal law or (b) consent to the application of Proposition 65 or any other law to any other product.

1.6 No Admissions. Nothing in this Consent Judgment is or shall be construed as an admission by the Parties of any fact, conclusion of law, issue of law, or violation of law, nor shall compliance with the Consent Judgment constitute or be construed as an admission by the Parties of any fact, conclusion of law, issue of law, or violation of law. Nothing in this Consent Judgment shall prejudice, waive, or impair any right, remedy, argument, or defense the Parties may have in any other legal proceeding. This Consent Judgment is the product of negotiation and compromise, and is accepted by the Parties for purposes of settling, compromising, and resolving issues disputed in this action.

## 2. **DEFINITIONS**

- 2.1 "Covered Products" means the products identified in Section 6 of Exhibit A for Settling Defendant.
- 2.2 "Effective Date" means the date on which this Consent Judgment is entered by the Court.

## 3. INJUNCTIVE RELIEF

- 3.1 Reformulation of the Covered Products.
- 3.1.1. The ingredients of the Covered Products include both active and inactive ingredients subject to review and approval by the federal Food and Drug Administration (the "FDA") and other regulatory agencies, including without limitation regulatory agencies in the

European Union (the "E.U."). Settling Defendant has chosen to take the necessary steps to remove Cocamide DEA from the Covered Products pursuant to the process for reformulating products under the aforementioned regulatory regimes.

- 3.1.2. Settling Defendant will begin the reformulation process for the Covered Products by the Effective Date and, barring any unanticipated delays, will have the reformulation completed December 31, 2020. All Covered Products manufactured after January 1, 2021 will be reformulated to exclude Cocamide DEA as an ingredient, unless there are unanticipated regulatory delays in such reformulation, in which case such reformulation will occur at the earliest commercially reasonable and practicable date after January 1, 2021.
- 3.2. Meet and Confer. If the reformulation set forth in Section 3.1 of this Consent Judgment does not occur by December 31, 2020, Settling Defendant will either discontinue distribution of the Covered Products in California or the Parties will meet and confer regarding a possible modification to this Consent Judgment to address compliance by the Covered Products with Proposition 65, taking into consideration any factors the Parties consider relevant. If the Parties determine that this Consent Judgment must be amended, they will follow the procedures set forth in Section 3.4.
- 3.3. Preservation of Competitiveness. The intent of this Section is to protect the competitive interests of Settling Defendant arising from the Shefa's claims and to ensure that by settling the allegations in the Notice of Violation and the Complaint, Settling Defendant is not disadvantaged with respect to its competitors. Specifically, the Parties agree that should any agreement or consent judgment be entered into by Shefa, The California Office of Environmental Health Hazard Assessment, or the California Attorney General's Office concerning products similar to the Covered Products that contains provisions that would materially impact the terms of this Consent Judgment, such benefits shall be deemed to accrue to Settling Defendant. If the Parties determine that this Consent Judgment must be amended, they will follow the procedures set forth in Section 3.4.

- 3.4 Procedure for Amending this Consent Judgment. If this Consent Judgment must be amended, the Parties will follow the following procedure: First, this Consent Judgment shall be amended by a stipulation. Then, a new [proposed] order shall be submitted to the Court for approval, a copy of which shall be provided to the Attorney General's office five (5) business days prior to submission to the Court, to provide Settling Defendant the benefit thereof. Further, should there be a court decision involving any other person or entity that received a Proposition 65 60-Day Notice of Violation alleging that Cocamide DEA in products similar to the Covered Products and such decision is in whole or in part favorable to the defendant(s) in such action, then that decision shall be incorporated into this Consent Judgment by a stipulation and a new [proposed] order that shall be submitted to the Court for approval, a copy of which shall be provided to the Attorney General's Office five (5) business days prior to submission to the Court.
- 3.5 Governing Law. The terms of this Consent Judgment shall be governed by the laws of the State of California and apply within the State of California.
- 3.6 Potential Repeal of Proposition 65. In the event that Proposition 65 is repealed or is otherwise rendered inapplicable by reason of law generally, or as to the Covered Products, including without limitation the delisting of Cocamide DEA, then Settling Defendant may provide written notice to Plaintiff of any asserted change in the law, and with the exception of Section 5.1 below, have no further obligations pursuant to this Consent Judgment, with respect to, and to the extent that, the Covered Products are so affected. None of the terms of this Consent Judgment shall have any application to Covered Products sold outside of the State of California.

## 4. ENFORCEMENT

- 4.1 Shefa may, by motion or application for an order to show cause before the Superior Court of Alameda County, enforce the terms and conditions contained in this Consent Judgment.
- 4.2 Prior to bringing any motion or application to enforce the requirements of Section 3 above, Shefa shall provide Settling Defendant with a Notice of Violation and proof of purchase and a copy of any test results, which purportedly support the Notice of Violation.

4.3 The Parties shall then meet and confer regarding the basis for the anticipated motion or application in an attempt to resolve it informally, including providing Settling Defendant with a reasonable opportunity of at least thirty (30) days to cure any alleged violation. This Consent Judgment may only be enforced by the Parties.

### 5. PAYMENTS

- Payments by Settling Defendant. Within ten (10) business days of the Effective Date, Settling Defendant shall initiate the settlement payment (per the terms in ¶ 7) identified on Exhibit A. The total settlement amount for Settling Defendant shall be paid pursuant to the instructions outlined in Exhibit A (hereinafter "Total Settlement"). The funds paid by Settling Defendant shall be allocated, as identified in Exhibit A, between the following categories:
- 5.1.1 Civil Penalty. A civil penalty pursuant to Health & Safety Code § 25249.7(b) in the amount identified in Section 7 of Exhibit A, with such money to be apportioned by Shefa in accordance with Health & Safety Code § 25249.12 (25% to Shefa and 75% to the State of California's Office of Environmental Health Hazard Assessment).
- 5.1.2 Attorney's Fees and Costs. The Parties acknowledge that Shefa and its counsel offered to resolve this dispute without reaching terms on the amount of fees and costs to be reimbursed to them, thereby leaving the issue to be resolved after the material terms of the agreement had been settled. Shortly after the other settlement terms had been finalized, Settling Defendant expressed a desire to resolve Shefa's fees and costs. Settling Defendant agrees to pay Shefa and its counsel under the private attorney general doctrine codified at California Code of Civil Procedure section 1021.5, for all work performed through the mutual execution and the Court's entry of this Consent Judgment, including without limitation the fees and costs incurred as a result of investigating, bringing this matter to the Settling Defendant's attention, negotiating a settlement, and seeking court approval of the same. The amount of such fees and costs which shall be paid by Settling Defendant is set forth in Exhibit A. Payment shall be delivered to Daniel N. Greenbaum, Law Office of Daniel N. Greenbaum, 7120 Hayvenhurst Avenue, Suite 320, Van Nuys, CA 91406.

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## 6. MODIFICATION

- 6.1 Written Consent. This Consent Judgment may be modified from time to time by express written agreement of the Parties with the approval of the Court, or by an order of this Court upon motion and in accordance with law.
- 6.2 Meet and Confer. Any Party seeking to modify this Consent Judgment shall attempt in good faith to meet and confer with all affected Parties prior to filing a motion to modify the Consent Judgment.

## 7. CLAIMS COVERED AND RELEASED

7.1 Mutual Release. This Consent Judgment is a full, final, and binding resolution between (a) on the one hand, Shefa on behalf of itself and the public interest; and, (b) on the other hand, (i) Settling Defendant; (ii) Settling Defendant's current, future, and former affiliates ("affiliate" means a person who, or entity which, directly or indirectly, fully or partially, owns or controls, is owned or controlled by, or is under common ownership or control with, Settling Defendant), including without limitation Patriot Pharmaceuticals, LLC; (iii) current, future, and past directors, officers, employees, and attorneys of Settling Defendant and Settling Defendant's current, future, and former affiliates (collectively, the persons and entities identified in Section 7.1(b)(i), (ii), and (iii) shall be referred to as the "Defendant Releasees"); (iv) each person to whom, or entity to which, any of the Defendant Releasees directly or indirectly distributes or sells Covered Products, including but not limited to distributors, wholesalers, customers, retailers, franchisees, cooperative members, licensors, and licensees ("Downstream Releasees"); (v) each person who, or entity which, directly or indirectly distributes or sells Covered Products, to any of the Defendant Releasees or Downstream Releasees, including but not limited to distributors, wholesalers, customers, retailers, franchisees, cooperative members, licensors, and licensees ("Upstream Releasees"); and (vi) each person who, or entity which, manufactures or packages (collectively "Manufacturers") the Covered Products, of any violation of Proposition 65 that was or could have been asserted in the Complaint against Settling Defendant, Defendant Releasees, Downstream Releasees, Upstream Releasees, or Manufacturers based on failure to warn about alleged exposure to Cocamide DEA contained in Covered Products that were manufactured, distributed, or sold by Settling Defendant, Defendant Releasees, Downstream Releasees, Upstream Releasees, or Manufacturers prior to the Effective Date.

- 7.2 Compliance. Compliance with the terms of this Consent Judgment by Settling Defendant shall constitute compliance with Proposition 65 by Settling Defendant, Defendant Releasees, Downstream Releasees, Upstream Releasees, and Manufacturers, with respect to any alleged failure to warn about Cocamide DEA in Covered Products manufactured, distributed, or sold by Settling Defendant on or after the Effective Date.
- 7.3 Unauthorized Distribution or Sale. Distribution and/or sale (including without limitation, importation, internet sale, direct sale, and/or resale) of non-reformulated Covered Products in California by a person or entity which is not affiliated with and/or authorized by Settling Defendant to distribute and/or sell Covered Products in California shall not constitute non-compliance with Proposition 65 and/or non-compliance with this Consent Judgment by Settling Defendant, Defendant Releasees, Downstream Releasees, Upstream Releasees, and/or Manufacturers.
- 7.4 Meet and Confer Regarding Non-Compliance. Should Plaintiff become aware of the sale of non-reformulated Covered Products, then Plaintiff's counsel shall contact Settling Defendant's counsel and counsel for Plaintiff and Settling Defendant shall meet and confer regarding any alleged non-compliance with this Consent Judgment and/or any alleged violation of Proposition 65.
- 7.5 Plaintiff Individual Waiver. Plaintiff, in its individual capacity only and not in its representative capacity, also provides a release to Settling Defendant, Defendant Releasees, Downstream Releasees, Upstream Releasees, and Manufacturers, which release shall be effective as a full and final accord and satisfaction, as a bar to all actions, causes of action, obligations, costs, expenses, attorneys' fees, damages, losses, claims, liabilities and demands of Plaintiff of any nature, character or kind, whether known or unknown, suspected or unsuspected, arising out

[P<del>ROPOSE</del>D] CONSENT JUDGMENT AS TO JANSSEN PHARMACEUTICALS, INC. - JCCP No. 4765

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The stipulations to this Consent Judgment may be executed in counterparts and by 1 means of facsimile or portable document format (pdf), which taken together shall be deemed to 2 3 11.10 Each signatory to this Consent Judgment certifies that he or she is fully authorized by the Party he or she represents to stipulate to this Consent Judgment and to enter into and execute 5 the Consent Judgment on behalf of the Party represented and legally to bind that Party. 6 7 11.11 The Parties, including their counsel, have participated in the preparation of this Consent Judgment and this Consent Judgment is the result of the joint efforts of the Parties. 8 9 11.12 This Consent Judgment was subject to revision and modification by the Parties and has been accepted and approved as to its final form by all Parties and their counsel. 10 11.13 Accordingly, any uncertainty or ambiguity existing in this Consent Judgment shall 11 not be interpreted against any Party as a result of the manner of the preparation of this Consent 12 13 11.14 Each Party to this Consent Judgment agrees that any statute or rule of construction 14 15 providing that ambiguities are to be resolved against the drafting Party should not be employed in the interpretation of this Consent Judgment and, in this regard, the Parties hereby waive California 16 17 18 19 20 21 22 23 24 25 26 27 28

AS TO JANSSEN PHARMACEUTICALS, INC. - JCCP No. 4765

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## ORDER AND JUDGMENT

Based upon the stipulated Consent Judgment between Shefa LMV, LLC and Janssen Pharmaceuticals, Inc., the Parties' Consent Judgment is approved and the clerk is directed to enter judgment in accordance with the terms herein.

Dated: My 33 7017

Judge of the Superior Court

GEORGE C. HERNANDEZ, JR.

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# EXHIBIT A

#### EXHIBIT A

- 1. Name of Settling Defendant: Janssen Pharmaceuticals, Inc.
- 2. Name of Plaintiff: Shefa LMV, LLC
- 3. Person(s) to Receive Notices (Pursuant to Section 8.3):

TATRO TEKOSKY SADWICK LLP David B, Sadwick, Esq. 333 S. Grand Avenue, Suite 4270 Los Angeles, CA 90071

Telephone: (213) 225-7171
Facsimile: (213) 225-7151
E-mail: dsadwick@ttsmlaw.com

4. Complaint Naming Settling Defendant (Pursuant to Section 1.4):

Shefa LMV, LLC v. Farouk Systems, Inc., et al., Los Angeles County Superior Court No. BC579191

- 5. Types of Covered Products:
  - X Shampoos (as more specifically described in Section 6 of this Exhibit A)
  - Soaps
- 6. Settling Defendant's Covered Products:

Ketoconazole; UPC: 1014707504 and all other prescription ketoconazole shampoos sold in California, manufactured for distribution in California, and/or distributed in California by Settling Defendant(s). Defendant Releasees, Downstream Releasees, Upstream Releasees, or Manufacturers

7. Settling Defendant's Settlement Payment and Allocation (Pursuant to Section 5.1):

Total Settlement Payment: \$50,000 Civil Penalty (payable to Shefa LMV, LLC): \$12,000 Payment in Lieu of Civil Penalty (payable to Shefa): \$ N/A Shefa Fees and Costs (payable to the Law Office of Daniel N. Greenbaum): \$38,000

Checks payable to "Shefa LMV, LLC" or the "Law Office of Daniel N. Greenbaum" shall be delivered to counsel for Shefa as set forth in Section 8.1.