28 May 2026

Jill Lindstrom, MD, Director
Division of Dermatology and Dentistry
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research
Food and Drug Administration
via Electronic Submissions Gateway

RE: NDA 022408, eCTD Sequence No. 0113
Natroba (spinosad) Topical Suspension, 0.9%

Response to PREA Non-compliance Letter

Dear Dr. Lindstrom,

Reference is made to New Drug Application (NDA) 022408 for Natroba (spinosad) Topical Suspension, 0.9% w/w, approved on 18 January 2011.

Reference is also made to the Notification of Non-compliance with PREA, dated 23 April 2026 (Reference ID: 5786011). Cipher Pharmaceuticals Inc. (Cipher) is submitting this response to the Notification of Non-compliance with PREA in accordance with the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 355c(d)(1)].

Further reference is made to the [redacted (b) (4)] requested by the FDA (SN0105). Subsequently, the [redacted (b) (4)] request was denied by the FDA, as stated in the letter received on 23 April 2025 (Reference ID: 5577159) and a protocol revision was requested.

Cipher acknowledges the FDA's determination that they have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because a pediatric assessment has not been submitted for the following PMR:

> **4062-1**: *A Single Treatment, Pharmacokinetic and Safety Study of Natroba (spinosad) Topical Suspension 0.9% w/w in Subjects 1 Month to 3 Years 11 Months of Age with an Active Scabies Infestation (SPN-110-21)*

Due to a protocol revision required as a result of [redacted (b) (4)] letter received by the FDA on 23 April 2025, a new amended final protocol will need to be submitted.

The company is in the process of updating the protocol with FDA's recommendations and assessing new sites to reopen enrollment. Cipher expects to submit the revised protocol by [redacted (b) (4)], as well as start study enrollment by [redacted (b) (4)]. A revised Study Completion date of [redacted (b) (4)] and revised Final Report Submission date of [redacted (b) (4)] has been established.

This submission has been prepared in electronic Common Technical Document (eCTD) format and is being submitted through the FDA's Electronic Submissions Gateway Next Generation (ESG NextGen) under (b) (4)'s approved Unified Submission Portal (USP) account. (b) (4). certifies that precautions have been taken to ensure that the eCTD is free of computer viruses and authorizes the FDA to use antivirus software, as appropriate.

If you should require further information, please contact me at VCLS Inc.'s telephone line dedicated to FDA (908-704-1691, ext. 288) or at amital@voisinconsulting.com.

Sincerely,

Allison Mital
Digitally signed by Allison Mital
Date: 2026.05.20 13:53:57 -04'00'

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