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July 15, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room1061 (HFA-305)
Rockville, MD20852

Citizen Petition

Dear Sir/Madam,

The under signed submits this petition on behalf of a client in accordance with 21 CFR parts 10.25, 10.30, and pursuant to Sections 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR parts 314.122 and 314.161 requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Nipride® RTU (sodium nitroprusside), 10 MG/50 ML (0.2 MG/ML), (NDA 209387) held by EXELA PHARMA SCS LLC has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products. Nipride® RTU (sodium nitroprusside), 10 MG/50 ML (0.2 MG/ML), held by EXELA PHARMA SCS LLC was approved by the FDA on December 7, 2017. The product was then considered to be a "listed drug product" in the Orange Book. Nipride® RTU (sodium nitroprusside), 10 MG/50 ML (0.2 MG/ML) now appears in the "Discontinued Section" of the Orange book (see attachment A).

Under current FDA regulations, drugs are removed from the Orange Book list if the Agency withdraws or suspends approval of the drug product's applications for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

It is requested that the FDA determine whether the NDA holder for Nipride® RTU (sodium nitroprusside), 10 MG/50 ML (0.2 MG/ML) has withdrawn the product for reasons of safety or effectiveness.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, Petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Lund, Boyd M

Digitally signed by Lund, Boyd M
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Enclosures