September 28, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Nicardipine Hydrochloride Injection
Submission Type: Citizen Petition – RLD Designation
Size: 15.2 Megabytes

Dear Sir/Madam:

The following citizen petition is being submitted by Alston & Bird LLP.

Citizen Petition

The undersigned submits this Citizen Petition under 21 CFR l0.25(a) and 21 CFR 10.30 as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act (FD&C) or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10, to request the Commissioner of the Food and Drug Administration to designate Nicardipine Hydrochloride Premixed Injection, 0.1 mg/mL and 0.2 mg/mL, in 0.9% Sodium Chloride manufactured by Exela Pharma Sciences under NDA 022276 and approved in April 2016 by FDA under 505(b)(2) process as alternative Reference Listed Drugs (RLDs).

A. Action Requested

The petitioner (Alston & Bird LLP) requests that the Commissioner of the Food and Drug Administration designate Nicardipine Hydrochloride Premixed Injection, 0.1 mg/mL and 0.2 mg/mL, in 0.9% Sodium Chloride manufactured by Exela Pharma Sciences under NDA 022276 as alternative RLDs for the purposes of submitting an Abbreviated New Drug Application ("ANDA") for generic versions of the drug products.

B. Statement of Grounds

FD&C Act and 505(j) allows the marketing of generic versions of previously approved drug products when the generic product is subject of an ANDA. To obtain ANDA approval, the applicant must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug has the same active ingredient(s) in the same strength, dosage form and route of administration, has essentially identical labeling and is bioequivalent.

A "listed drug" includes a new drug product that has an effective approval under FDC Act 505(j), that has not been withdrawn or suspended under FD&C Act 505(e)(I), that through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21 CFR 314.3. Listed drugs are identified in FDA's Orange Book. An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application.

In the case of Nicardipine Hydrochloride, the Orange Book identifies the drug products manufactured by Chiesi USA Inc. under NDA 019734, Cardene in 0.86% Sodium Chloride in Plastic Container, 20 mg in 200 mL (0.1 mg/mL) and Cardene in 0.83% Sodium Chloride in Plastic Container, 40 mg in 200 mL (0.2 mg/mL), as the RLDs. The drug formulations for Sodium Chloride are different from the intended formulation our client plans to produce and submit in their ANDA application (i.e. 0.9% versus 0.86% and 0.83%) and according to CFR 21 314.94, their formulation has to be Q1/Q2 to the RLD formulation. For this reason, our client believes that the drug formulation for the drug products manufactured by Exela would be more suitable RLDs for their ANDA application, but since the Chiesi designated RLDs have a different formulation and since there is currently no RLD designated for the 0.9% drug formulation, their ANDA development and application have been delayed until an agreement can be reached with FDA regarding a suitable RLD. With regards to the active ingredients, drug strengths, dosage form, route of administration, labeling and bioequivalence, our client's product exactly matches the drug products manufactured by both the approved RLD, Chiesi and by Exela.

We also believe this request is reasonable even though the application and approval for the Exela products was done under the 505(b)(2) process. In the current Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions, January 2017, it states that "to ensure that a drug product approved in a 505(b)(2) application is not shielded from generic competition, FDA may designate the drug product approved in a 505(b)(2) application as an additional RLD if requested to do so."

Accordingly, the Petitioner respectfully requests the FDA to designate Nicardipine Hydrochloride Premixed Injection, 20 mg in 200 mL (0.1 mg/mL), NDC 0143-9634-01 and 40 mg in 200 mL (0.2 mg/mL), NDC 0143-9633-01 in 0.9% Sodium Chloride manufactured by Exela Pharma Sciences under NDA 022276 as alternative RLDs.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

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 that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Yours truly,

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cc: Dan Jarcho, Alston & Bird LLP