Herbert Nemteanu, B. Sc., MBA
Odan Laboratories, Inc.
325 Stillview Avenue
Pointe-Claire, QC, Canada H9R 2Y6

Sent via email to: ggallo@odanlab.com

Docket No. FDA-2006-P-0457
Legacy Docket No. 2006P-0230/CP1

Dear Mr. Nemteanu:

This is in response to your petition received on June 6, 2006, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Lidocaine Hydrochloride Non-aerosol Spray, 12 mg. The listed drug product to which you refer in your petition is Xylocaine (Lidocaine) Oral Spray, 10%, approved under New Drug Application (NDA) 014394 and held by AstraZeneca, L.P.

Your petition requests a change in dosage form and active ingredient from that of the listed drug product (i.e., from aerosol oral spray to non-aerosol oral spray, and from lidocaine to lidocaine hydrochloride). Your requested change in dosage form is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug and Cosmetc Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, your requested change from lidocaine to lidocaine hydrochloride is not a type of change for which the Agency will accept a petition under section 505(j)(2)(C) of the Act and the implementing regulations at 21 CFR 314.93, which only allow for certain differences in active ingredient (when in a combination product) or route of administration, dosage form, or strength from that of a listed drug. Because the change in active ingredient that you request is not one of the permissible types of changes, the Agency denies your request.

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to

assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)]."). Because you are seeking a change in dosage form and active ingredient, this proposed product triggers PREA.

This petition is being denied because the requested change in active ingredient from lidocaine to lidocaine hydrochloride is not a type of change for which the Agency will accept a petition. Therefore, because your petition does not meet the applicable requirement under section 505(j)(2)(C) of the Act and 21 CFR 314.93, it is not necessary to address the question of whether pediatric studies are necessary under PREA. Please contact the Office of New Drugs' Division of Anesthesiology, Addiction Medicine, and Pain Medicine at (301) 796 – 2280 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
Date: 2024.11.06 11:58:04 -05'00'

William Chong
Director, Office of Safety and Clinical Evaluation
for Iilun Murphy
Director

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