DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-751/S-013

Tolmar, Inc.
Attention: Laura Eder, Sr. Regulatory Associate
701 Central Avenue
Fort Collins, CO 80526

Dear Ms. Eder:

Please refer to your supplemental new drug application dated April 28, 2008, received April 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atridox® (doxycycline hyclate) Periodontal System, 10% for the treatment of chronic adult periodontitis.

We acknowledge receipt of your submissions dated November 12, 2008, March 19, April 28, May 6 and 11, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change to the secondary packaging from pouches to trays.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA Supplement 50-751/S-013."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for

approved NDA Supplement 50-751/S-013." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sue Kang, Regulatory Project Manager, at (301) 796-4216.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drugs Evaluation and Research

Enclosure: labeling
carton and immediate container labels

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich

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