

August 4, 2017¹

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: Citizen Petition

To Whom It May Concern:

The undersigned submit this petition to request the Commissioner of Food and Drugs to initiate the public rulemaking process for reviewing and updating several over-the-counter (OTC) drug monographs for oral health drug products.

A. ACTION REQUESTED

The undersigned submit this petition to request the Commissioner of Food and Drugs to initiate the public rulemaking process for reviewing and updating the following over-the-counter (OTC) drug monographs for oral health drug products.

- OTC Anticaries Drug Products (21 CFR Part 355)
- OTC Oral Healthcare Drug Products (21 CFR Part 356)
- OTC Oral Wound Healing Drug Products (21 CFR Part 356)
- OTC Nailbiting and Thumbsucking Drug Products (21 CFR 310.536)
- OTC Internal Analgesic Drug Products (21 CFR Part 343)

B. STATEMENT OF GROUNDS

Many of the oral health-related OTC drug monographs have not kept pace with latest science-based testing standards. As a result, consumers are buying a new generation of OTC oral health products whose safety, identity, strength, quality, and purity are based on decades old science.

For example, the monograph for OTC anticaries drug products (products that aid in the prevention of dental cavities) has not been updated since 1995. Newer and better tests are available to evaluate the safety, identity, strength, quality, and purity of these products (e.g., one minute fluoride release test in fresh and aged samples). However, the FDA monograph requires that these products still be evaluated using decades old tests that are outdated and no longer necessary (e.g., caries reduction studies in animals).

¹ This petition was originally submitted and received in Regulations.gov on August 2, 2017. See Comment Tracking Number 1k1-8xv7-ehcq.

Moreover, it would be in line with the recently proposed revision to the FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioids to update the drug monograph for OTC pain relievers, which dentists often advise patients to use for post-operative dental pain (in lieu of opioid analgesics). (See the attached comments in response to Docket No. FDA-2017-D-2497.)

We would all benefit from knowing that the oral health-related drug products sold OTC have met the latest and best available scientific standards for safety, identity, strength, quality, and purity. Updating these drug monographs would be an important step in that direction.

C. ENVIRONMENTAL IMPACT

The action(s) requested are categorically excluded from the requirement to provide an EA or EIS under 21 CFR § 25.31.

D. ECONOMIC IMPACT

It is our understanding that this information is to be submitted only when requested by the Commissioner following review of the petition.

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 are unfavorable to the petition.

American Dental Association
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202-898-2400

If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

/s/

Gary L. Roberts, D.D.S.
President

/s/

Jeffrey A. Platt, D.D.S., M.S.
Chair, Council on Scientific Affairs

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

/s/

Marcelo Araujo, D.D.S., M.S., Ph.D.
Vice President, Science Institute

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