



January 3, 2014

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

Re: Docket No. FDA-2011-N-0898

To Whom It May Concern:

The American Dental Association (ADA) and the American Association of Oral and Maxillofacial Surgeons (AAOMS) are pleased to jointly comment on the proposed Food and Drug Administration (FDA) rule requiring applicants of covered approved drugs or biological products to electronically notify FDA of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply. We offer these comments in response to your Federal Register notice of November 4, 2012 (78 FR 65904).

As you can see from our enclosed comments, our organizations are generally pleased with the proposed rule. We are especially pleased with the proposal to equate the term "debilitating disease or condition" with "serious disease or condition" (found in 21 CFR 312.300).

We welcome opportunities to continue working with FDA on this issue. If you have any questions, please contact Mr. Robert J. Burns at the American Dental Association. Bob can be reached at 202-789-5176 or burns@ada.org.

Sincerely,

Charles H. Norman, D.D.S.
President
American Dental Association

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

Eric T. Geist, D.D.S.
President
American Association of
Oral and Maxillofacial Surgeons

Robert C. Rinaldi, Ph.D., C.A.E.
Executive Director
American Association of
Oral and Maxillofacial Surgeons

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Supplementary Comments on the Permanent Discontinuance or Interruption in the Manufacturing of Certain Drug or Biological Products

The American Dental Association (ADA) and the American Association of Oral and Maxillofacial Surgeons (AAOMS) are pleased to jointly comment on the proposed Food and Drug Administration (FDA) rule requiring applicants of covered approved drugs or biological products to electronically notify FDA of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply.

- **Scope of products subject to the notification requirement.** We urge you to clarify that drugs used to treat a “debilitating disease or condition” include sedatives, anesthetics, analgesics and anti-inflammatory drugs.

The current proposal—to equate the term “debilitating disease or condition” with “serious disease or condition” (found in 21 CFR 312.300)—will inherently require manufacturers to provide advanced notification of potential shortages of these drugs. To avoid any confusion, however, we urge you to clarify that point by expressly identifying sedatives, anesthetics, analgesics and anti-inflammatory drugs as being covered in the final rule and any corresponding guidance documents.

- **Dissemination of information.** While this proposed rule would certainly improve stakeholder notification of shortages by enhancing the amount of information disseminated by the FDA, it would be beneficial for such notifications to avoid a “one-size-fits-all” information delivery method. Instead of simply notifying all stakeholders of every shortage, we suggest allowing for specialty-specific notifications. Just as it is possible for stakeholders to receive specialized FDA product recall alerts, the same should be done for drug shortage alerts. This would provide the same benefits and increased specificity regarding drug shortages as the recall alerts that are currently enjoyed by specialty organizations.

In addition, we submit the following comments that may be helpful to resolving discontinuances and interruptions in manufacturing of shortage drugs, as well as FDA considerations for more effectively communicating with stakeholders about shortages.

- **Distributional shortages.** As national healthcare provider organizations, we are routinely notified by our members of drug shortages they experience in their practices. However, we have noticed that those shortages are not always being reported by the FDA. One reason for this discrepancy might be that while certain drugs are readily available to hospitals, they are not readily available to smaller scale establishments such as surgical centers (where many of our members practice) or individual provider offices. This could cause some shortages to go undiscovered by the FDA. Although we are not prepared to speak on the reason(s) why this occurs, we ask for FDA clarification. FDA investigation into this phenomenon may offer an opportunity to help stakeholders like us and our members better deal with drug shortages and collaborate with the FDA to alleviate them.
- **Drug shortage disclosures.** It has come to our attention that FDA product recalls are periodically the cause of drug shortages. As a result of such cases, we suggest that the FDA establish a clearer link between the two. It would be helpful to organizations

tracking product recalls and drug shortages if the FDA provided information about the potential for a drug shortage due to a product recall when they disseminate recall notices. Likewise, drug shortage notifications could include a disclosure indicating that the shortage was caused, in whole or in part, by an associated product recall. Not only would this provide more information to stakeholders about a particular shortage, but it would also be helpful to the FDA in working with applicants to resolve discontinuances or interruptions in manufacturing.

- **Stakeholder input.** This proposed rule significantly increases the amount and specificity of information disseminated by the FDA to stakeholders when there is a drug shortage. One of the pieces of information that will be disseminated following the finalization of this proposed rule will be a recommended alternative to the drug in shortage. In an attempt to improve communication between stakeholders and the FDA about drug shortages, we suggest that FDA create an avenue for certain stakeholders, like healthcare professional associations, to offer expert advice to the FDA in this area. There is not a more infallible way that we can devise to ensure the best possible alternative drug is endorsed by FDA than if that drug is advanced by providers who use it regularly and have been trained on its efficacy.