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June 2, 2021

Theresa M. Michele, M.D.
Director
Office of Nonprescription Drugs
U.S. Food and Drug Administration (FDA)
Via email

Re: Request for agency exercise of enforcement discretion regarding addition of new Warning language to *Drug Facts* labeling for Over-the-Counter Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Dear Dr. Michele:

The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and distributors of over-the-counter (OTC) medicines in the U.S. CHPA, on behalf of individual members marketing OTC internal analgesic monograph NSAIDs (ex., aspirin; salicylates), is writing to request that FDA exercise its enforcement discretion and not take enforcement action against companies choosing to include a warning related to pregnancy (see below) on monograph product labels.

On April 28, 2021, FDA wrote to holders of products approved under a new drug application (NDA or sNDA) requesting a modification of the warning language for pregnancy. It is in the interest of public safety that this language be modified on all OTC internal analgesic monograph NSAID products, not only those approved under an NDA or sNDA. We encourage FDA to make use of its new authority under OMUFA to issue a proposed order to request this change in labeling. In the meantime, we are requesting that FDA allow manufacturers to make this change now, in advance of official action by FDA, on all these NSAID products. Given the large number of products impacted, manufacturers need maximum possible lead time to ensure these changes take place in an orderly and timely fashion.

The change being made is shown below:

Under the “**If pregnant or breast-feeding**” warning, replace “during last 3 months of” with “at 20 weeks or later in”. The revised warning reads as:

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use [insert NSAID ingredient(s)] at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.



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Sincerely,

A handwritten signature in black ink that reads "Barbara A. Kochanowski". The signature is written in a cursive style with a large initial "B" and "K".

Barbara A. Kochanowski, Ph.D.
SVP, Regulatory & Scientific Affairs
BKochanowski@CHPA.org

Cc: Donald Ashley
Valerie Pratt