CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

April 12, 2019

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

Re: Draft guidance on smoking cessation and related indications: developing nicotine replacement therapy drug products; request for comments (Docket No. FDA-2019-D-0297), 84 Fed. Reg. 5693 (February 22, 2019)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the above captioned draft guidance on indications for nicotine replacement therapies (NRT). CHPA, founded in 1881, is the national trade association representing manufacturers of over-the-counter (OTC) or nonprescription medicines and dietary supplements in the United States. A number of our member companies hold new drug applications or abbreviated new drug applications for NRT. As such, we have an interest in the subject matter of FDA's draft guidance.

Our comments cover two areas:

1. General themes on helping people quit smoking and stop tobacco use; and
2. Comments specific to the draft guidance.

1. General themes on helping people quit smoking and stop tobacco use. Similar to our previous comments to the agency on NRT and smoking cessation, including at FDA's January 26, 2018, public hearing, we were pleased that the draft guidance emphasizes the importance of developing additional NRT products, which could help more smokers quit. For the past 20 years, having products to stop smoking at least as accessible as those that create nicotine addiction has demonstrated a public health gain. For instance, NRT OTC availability led to over 400,000 more quit attempts and a 152% increase in NRT-assisted quit attempts the first year following the prescription-to-OTC switch.[1]

The draft guidance is notable in that allowing secondary claims and an additional primary endpoint acknowledge a reality: Quitting smoking provides the greatest personal and public health benefit, but it is evident that smokers or, more broadly, tobacco users, aren't all the same.

[1]Theodore Keeler, et al., *The benefits of switching smoking cessation drugs to over-the-counter status*, 11 Health Economics 389 (January 2002); Saul Shiffman, et al., *Public health benefit of over-the-counter nicotine medications*, 6 Tobacco Control 306 (1997).

The path to quit may be shorter or longer. It may be one of abstinence or relapse with multiple attempts. It may be one of limiting exposure, including steps. The fact that an average smoker takes five to seven quit attempts before success only underscores how complex this path can be.

We agree with the agency that stopping smoking – cessation – should remain the objective, while secondary endpoints can help individuals on that path.

2. Comments specific to the draft guidance.

Eligibility for expedited pathways: We agree with the agency's rationale for potential eligibility for review under FDA's expedited development and review pathways, and encourage FDA to retain this discussion in a final guidance.

Pragmatism on changes to current products: We were encouraged by the pragmatism in a number of areas throughout the draft guidance. For instance, FDA references the need for one study as opposed to two, along with appropriate bridging to existing data, for secondary endpoints, for different instructions for use, and new modes of administration if there is an appropriate reference product. We encourage FDA to retain these elements in a final guidance.

Additional efficacy endpoints: We applaud FDA's openness to consider data to support additional efficacy endpoints, including reduction in risk of relapse as a primary endpoint, as well as secondary endpoints on reduction of urge to smoke, relief of cue-induced craving, and relief of withdrawal symptoms not associated with a cessation attempt. While we welcome FDA's openness on these specifically-referenced secondary indications, we also urge the agency to remain open to other secondary indications. For instance, the draft guidance references reduce to quit as a regimen as opposed to an indication, and doesn't reference cessation of non-cigarette tobacco products as a specific indication. Rather than attempting to list any and all specific indications, the guidance could reference the opportunity to submit stream-lined data packages (including label comprehension) for these supplemental claims to products approved with a primary endpoint indication.

Thank you for the opportunity to provide these comments. CHPA members want to do their part in making tobacco-related death and disease part of America's past.

Respectfully submitted,

David C. Spangler
Senior Vice President, Policy,
& General Counsel

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