DOCKET NO. FDA–2016–N–2523

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE STATUS OF VINPOCETINE

November 7, 2016

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including herbal dietary supplements. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On September 7, 2016 the Food and drug Administration (FDA or the Agency) issued a Federal Register notice (the September 7 Notice) in which it requested comments related to the regulatory status of vinpocetine, and specifically on the Agency's tentative conclusion that vinpocetine is not a dietary ingredient and is excluded from the definition of dietary supplement in the Federal Food, Drug, and Cosmetic Act (FD&C Act). AHPA submits these comments in the interest of companies that currently market dietary supplements that contain vinpocetine and its members generally.

FDA's prior attention to vinpocetine as a dietary ingredient has included responses to five separate new dietary ingredient (NDI) notifications submitted by four companies between 1997 and 1999; conditions of use identified in these notifications included daily consumption levels of from 5 (five) to 30 (thirty) milligrams daily. FDA did not identify any significant concerns or objections to any of these notifications and dietary supplements containing vinpocetine are currently broadly marketed.

I. Vinpocetine and Section 201(ff)(1) of the FD&CA

FDA expressed in the September 7 Notice its tentative conclusion that vinpocetine is not a dietary ingredient under section 201(ff)(1) of the Food, Drug & Cosmetics Act (FD&CA).

More specifically, the agency stated that it is not aware of any argument that vinpocetine is either a vitamin, mineral or amino acid and so does not appear to qualify as a dietary ingredient under sections 201(ff)(1)(A), (B), or (D), respectively; that vinpocetine is not an herb or other botanical or a constituent of a botanical and so does not appear to qualify as a dietary ingredient under sections 201(ff)(1)(C);

that, based on extensive database and literature searches that did not identify any food use of vinpocetine, the substance is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake and so does not appear to qualify as a dietary ingredient under sections 201(ff)(1)(E); and that vinpocetine is not a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient and so does not appear to qualify as a dietary ingredient under section 201(ff)(1)(F).

AHPA wishes to comment on just one of the details in FDA's above described assertions, and suggests the agency clarify that even though its database and literature searches did not identify any food use of vinpocetine such use was possibly overlooked or could come into use in the future. For example, a food manufacturer may establish vinpocetine as generally recognized as safe and add the ingredient to a food, at which time vinpocetine would qualify as a dietary ingredient under section 201(ff)(1)(E) of the FD&CA.

AHPA therefore strongly encourages FDA to clarify that if vinpocetine is either found to be currently in the market as a food ingredient or comes to be included as a food ingredient in the future the ingredient would therefore qualify as a dietary ingredient under section 201(ff)(1)(E) of the FD&CA.

II. Vinpocetine and Section 201(ff)(3) of the FD&CA

FDA expressed in the September 7 Notice its tentative conclusion that vinpocetine is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&CA. The Agency articulated the basis for this position by noting that, under section 201(ff)(3)(B)(ii) of the FD&C Act, a dietary supplement cannot include "an article authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public" unless the article was marketed as a dietary supplement or as a food before such authorization. The Agency also noted that vinpocetine was authorized by FDA for investigation as a new drug in 1981 and that several reports on clinical studies of vinpocetine were publish in trade press and other media outlets between 1985 and 1987.

AHPA notes that the relevant provision of the FD&CA, section 201(ff)(3)(B)(ii), reads in full as follows (with emphasis added):

> "[The term 'dietary supplement' does not include] an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food ***unless the Secretary [Health & Human Services], in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter***."

Thus it can be seen from the above emphasized clause that the United States Congress provided the Secretary of Health & Human Services (HHS) with authority to create exceptions to the normal exclusion from the definition of a dietary supplement of articles described in the above cited paragraph. Although this authority has not been used in the 22 years since this statutory provision was established, it should be assumed that the Congress foresaw that there might be circumstances in which it would be appropriate for the Secretary HHS to undertake the described regulatory steps to create such an exception.

Given the present circumstances – that vinpocetine has been the subject of five NDI notifications on which FDA expressed no significant concerns or objections and that the ingredient is currently broadly sold – AHPA believes that vinpocetine should be recognized as a reasonable subject for the exception allowed for under the law.

AHPA therefore strongly recommends that the Agency recommend and encourage the Secretary HHS to consider exercising her authority in this matter by initiating rulemaking to declare vinpocetine to be lawful under the cited chapter if the ingredient is determined to otherwise meet the definition of a dietary ingredient as discussed in part I of these comments.

AHPA greatly appreciates the opportunity to present comments on this matter. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if

clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

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