Page 9 – Mr. Seymour, Viracor-IBT Laboratories, Inc.

that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Zika Virus Real-time RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Zika Virus Real-time RT-PCR test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21353 Filed 9–6–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2523]

Request for Comment on the Status of Vinpocetine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting comments related to the regulatory status of vinpocetine. Specifically, we request comments on our 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). This action is being taken as part of an administrative proceeding to determine the regulatory status of vinpocetine. All comments submitted by the comment deadline (see **DATES**) will be accepted as part of the official record for this proceeding.

DATES: Submit either electronic or written comments on the notice by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2523 for ''Request for Comment on the Status of Vinpocetine.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cara Welch, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2333.

SUPPLEMENTARY INFORMATION:

I. Introduction

We are initiating an administrative proceeding under 21 CFR 10.25(b) to determine the regulatory status of vinpocetine (chemical name: Ethyl apovincaminate). Specifically, we are trying to determine: (1) Whether vinpocetine is a dietary ingredient within the meaning of the FD&C Act and (2) whether it is excluded from being a dietary supplement under the FD&C Act.

A. Statutory Background

Under section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)), the term ''dietary supplement'' is defined in part as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) A vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

Additionally, 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.

Recently, questions have been raised as to whether vinpocetine is a dietary ingredient and is excluded from the definition of dietary supplement under sections 201(ff)(1) and (3) of the FD&C Act, respectively.

B. Factual Background

According to records on file in FDA's Center for Drug Evaluation and Research, vinpocetine was authorized for investigation as a new drug in 1981.[1] A trade press article from 1985 reported that four single-center phase 3 clinical trials[2] of vinpocetine had been completed and that two major multicenter studies were ongoing (Ref. 1). A 1986 article in a major newspaper reported that Ayerst had recently completed a study of vinpocetine for the treatment of multiple-infarct dementia at eight institutions in the United States (Ref. 2). An article published in a medical journal in 1986 reported on the results of a double-blind study of vinpocetine in elderly patients with central nervous system degenerative disorders (Ref. 3). A trade press article published in 1988 reported that vinpocetine was in phase 3 clinical trials for Alzheimer's disease (Ref. 4). These articles document that substantial clinical investigations of vinpocetine were instituted and that the existence of these substantial clinical investigations was made public.

On July 8, 1997, a new dietary ingredient notification[3] for vinpocetine was submitted to FDA (see FDA's Table of New Dietary Ingredient Notifications

[1] An article becomes ''authorized for investigation as a new drug'' after the sponsor has submitted an investigational new drug application (IND) to FDA and the IND has gone into effect. Unless FDA notifies the sponsor that the clinical investigation described in the IND has been placed on clinical hold, the IND goes into effect 30 days after being submitted to FDA (21 CFR 312.40(b)). Although FDA will not disclose the existence of an IND that has not previously been publicly disclosed or acknowledged (see 21 CFR 312.130), the existence of the 1981 IND for vinpocetine was publicly disclosed in the press no later than 1986 (Ref. 2).

[2] Generally speaking, under our regulations pertaining to investigational new drugs, there are three phases of a clinical investigation of a new drug; phase 3 trials are the last in the sequence and are ''expanded controlled and uncontrolled trials'' that are ''performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling'' (21 CFR 312.21(c)).

[3] As defined in section 413(d) of the FD&C Act (21 U.S.C. 350b(d)), the term ''new dietary ingredient'' means a dietary ingredient that was not marketed in the United States before October 15, 1994. Section 413(a) of the FD&C Act (21 U.S.C. 350b(a)) requires manufacturers and distributors who wish to market dietary supplements that contain ''new dietary ingredients'' to submit a notification containing safety information to FDA before they begin marketing, unless the new dietary ingredient and all other dietary ingredients in the dietary supplement have been present in the food supply, without chemical alteration, as articles used for food.

(available on the Web at *http://www.fda.gov/food/dietarysupplements/newdietaryingredients notificationprocess/ucm109764.htm#new_din*)). Four additional new dietary ingredient notifications for vinpocetine were later submitted to FDA.[4]

C. Vinpocetine and Section 201(ff)(1) of the FD&C Act

We first consider whether vinpocetine is a dietary ingredient under section 201(ff)(1) of the FD&C Act—specifically, whether it is a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of dietary ingredients from the preceding categories. We are not aware of any argument that vinpocetine is a vitamin, a mineral, or an amino acid. Thus, vinpocetine does not appear to qualify as a dietary ingredient under section 201(ff)(1)(A), (B), or (D) of the FD&C Act.

Vinpocetine is not an herb or other botanical, nor is it a constituent of any botanical. Rather, vinpocetine is a synthetic compound, derived from vincamine, an alkaloid found in the *Vinca minor* plant, or tabersonine, an alkaloid found in Voacanga seeds (Ref. 5). Vinpocetine can be formed synthetically from vincamine, including via a ''one-pot'' synthesis, through transesterification and/or dehydration of vincamine in ethanol using Lewis acids and catalyzed by ferric chloride (Refs. 5 and 6). The process to prepare vinpocetine from tabersonine involves first converting to vincamine via hydrogenation, oxidation, reduction and, finally, isolation of vincamine (Ref. 7). The previously discussed method of producing vinpocetine from vincamine can then be used. As a synthetic compound, vinpocetine is not an herb or other botanical. Thus, vinpocetine does not appear to qualify as a dietary ingredient under section 201(ff)(1)(C) of the FD&C Act.

Vinpocetine is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Extensive database and literature searches did not identify any food use of vinpocetine. Thus, vinpocetine does not appear to qualify as a dietary ingredient under section 201(ff)(1)(E) of the FD&C Act.

Finally, vinpocetine is not a concentrate, metabolite, constituent, extract, or combination of any ingredient described in section 201(ff)(1)(A), (B), (C), (D), or (E) of the FD&C Act. We are not aware of any factual basis to conclude that vinpocetine is a concentrate, metabolite, constituent, extract, or combination of a vitamin, mineral, amino acid, or dietary substance. As described earlier, vinpocetine is not found in *V. minor,* Voacanga, or any other botanical, but rather is a synthetic derivative of vincamine or tabersonine. Therefore, vinpocetine cannot be a concentrate, constituent, or extract of a botanical. After extensive literature and database searches, we have been unable to find any evidence that vinpocetine is a concentrate, metabolite, constituent, extract, or combination of another dietary ingredient or dietary ingredients. Therefore, vinpocetine does not appear to qualify as a dietary ingredient under section 201(ff)(1)(F) of the FD&C Act.

We therefore tentatively conclude that vinpocetine is not a dietary ingredient under section 201(ff)(1) of the FD&C Act because it does not fit any of the dietary ingredient categories.

D. Vinpocetine and Section 201(ff)(3) of the FD&C Act

As noted above, the statutory definition of ''dietary supplement'' excludes an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or as a food before such authorization (see section 201(ff)(3)(B)(ii) of the FD&C Act).

Based on FDA's IND records and articles published between 1985 and 1988 that mention or report on phase 3 clinical trials for vinpocetine (Refs. 1 to 4), it appears that: (1) Vinpocetine was authorized for investigation as a new drug in 1981, long before the first new dietary ingredient notification for vinpocetine was filed in 1997 and, therefore, also long before vinpocetine was marketed as a dietary supplement; (2) substantial clinical investigations of vinpocetine have been instituted, and (3) the existence of such investigations has been made public.

We therefore tentatively conclude that vinpocetine is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act.

E. Tentative Conclusion

Based on the evidence available to us to date, we tentatively conclude that vinpocetine is not a dietary ingredient as defined in section 201(ff)(1) of the FD&C Act. We further tentatively conclude that vinpocetine is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act and therefore may not be marketed as or in a dietary supplement. We are interested in receiving information that would inform our final decision on the regulatory status of vinpocetine, such as information about any food uses of vinpocetine and information on the date vinpocetine was first marketed as a food or as a dietary supplement.

To afford all interested parties an adequate opportunity to participate in this matter, we request comments and other supporting information related to this matter. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document.

II. References

The following references are on display in FDA's Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. The Pink Sheet, ''Ayerst Planning on First Quarter 1986 NDA Submission for Alredase (Tolrestat) in Diabetic Neuropathy; Firm is Shooting for Early 1987 Market Launch,'' June 17, 1985. Retrieved from: *https://pink.pharmamedtechbi.com/PS008480/AYERST-PLANNING-ON-FIRST-QUARTER-1986-NDA-SUBMISSION-FOR-ALREDASE-TOLRESTAT-IN-DIABETIC-NEUROPATHY-F.*
2. Maugh II, T. H., ''Firm Hopes to Market New 'Memory' Drug,'' *The Los Angeles Times,* April 15, 1986. Retrieved from: *http://articles.latimes.com/1986-04-15/news/mn-4847_1_vinpocetine.*
3. Manconi, E., F. Binaghi, and F. Pitzus, ''A Double-Blind Clinical Trial of Vinpocetine in the Treatment of Cerebral Insufficiency of Vascular and Degenerative Origin,'' *Current Therapeutic Research,* Vol. 40, No. 4, 1986.
4. The Pink Sheet, ''American Home Products' 'Third Generation' TPA Entering Clinicals,'' March 21, 1988. Retrieved from: *https://pink.pharmamedtechbi.com/PS013359/AMERICAN-HOME-PRODUCTS-THIRD-GENERATION-TPA-ENTERING-CLINICALS.*
5. National Toxicology Program, U.S. Dept. of Health and Human Services, ''Chemical Information Review Document for Vinpocetine [CAS No. 42971–09–5].'' Retrieved from: *http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/vinpocetine091613_508.pdf.*
6. Y. Kuge, H. Nakazawa, T. Kometani, et al., ''A Facile One-Pot Synthesis of Vinpocetine,'' *Synthetic Communications:*

[4] We acknowledged receipt of each of those new dietary ingredient notifications without objection.

An Internal Journal for Rapid Communication of Synthetic Organic Chemistry, vol. 24, no. 6, 1994.
7. U.S. Patent and Trademark Office, ''Process of Preparation of Vincamine from Tabersonine.'' Retrieved from: *http://www.google.com/patents/US3892755.*

Dated: *August 31, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21350 Filed 9–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–new–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate below or any other aspect of the ICR. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before [November 7, 2016].

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–new–60D for reference.

Information Collection Request Title: National Tissue Recovery through Utilization Survey.

Abstract: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, requesting the Office of Management and Budget (OMB) approval on a new (ICR). This survey is being conducted to generate national estimates of recovery through utilization activity; of donated human tissue for calendar years 2012 and 2015, and to compare metrics across three data collection periods that includes results from a 2007 survey, the most recent year these data were collected. The survey and data collection and analysis methods will be similar to the 2007 survey. The general categories of information to be collected are listed under the Survey Section of the Annualized Burden Hour table below. Policy advice provided by the HHS Advisory Committee on Blood and Tissue Safety and Availability to the HHS Secretary and Assistant Secretary for Health is used to direct departmental efforts to address transfusion and transplantation issues; such as emergency preparedness and infectious disease transmission related to donated human tissue.

Likely Respondents: Respondents for this survey would be U.S. tissue banks that screen and recover tissue from living and deceased donors, and process, store, and/or distribute tissues grafts for transplantation from these donors.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Survey section	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Tissue bank activities, tissue types handled, and inspections.	All tissue banks	110	5	5/60	46
Referrals, authorization, and informed consent; tissue recovery and acquisition.	Tissue banks that handle referrals, Recover/acquire tissue.	80	36	30/60	1440
Tissue processing	Tissue banks that process tissue	35	17	30/60	298
Tissue storage	Tissue banks that store tissue	65	4	10/60	5
Tissue distribution	Tissue banks that distribute tissue	58	16	15/60	232
Communicable disease testing and adverse outcome reports.	Tissue banks that have donor infectious disease testing performed and may handle adverse outcome reports.	35	4	30/60	70
Total					2091

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2016–21360 Filed 9–6–16; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Office of Urban Indian Health Programs Strategic Plan

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice and request for comments.