

# **Exhibit 9**

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**From:** Amy Eichner, Ph.D. <AEichner@usada.org>  
**Sent:** Wednesday, December 01, 2010 7:18 PM  
**To:** Bestervelt, Lori; Wyszumiala, Edward  
**Subject:** RE: methylhexeneamine

never say die.

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From: Bestervelt, Lori [Bestervelt@nsf.org]  
Sent: Wednesday, December 01, 2010 6:33 PM  
To: Amy Eichner, Ph.D.; Wyszumiala, Edward  
Subject: Re: methylhexeneamine

That is lame and disappointing. Not ready to give up on this Sent via BlackBerry from T-Mobile

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From: "Amy Eichner, Ph.D." <AEichner@usada.org>  
Date: Wed, 1 Dec 2010 17:44:21 -0700  
To: bestervelt@nsf.org<bestervelt@nsf.org>; Wyszumiala, Edward<ewyszumiala@nsf.org>  
Subject: FW: methylhexeneamine  
looks like an uphill battle

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From: Levy, Dan [Dan.Levy@fda.hhs.gov]  
Sent: Wednesday, December 01, 2010 4:01 PM  
To: Amy Eichner, Ph.D.  
Cc: Moore, Robert J  
Subject: methylhexeneamine  
Dr. Eichner

Thank you for this information. Certainly if you have citations to published studies or other information that discusses the presence or absence of methylhexeneamine in extracts from Pelargonium spp. that you would like to share with us, we would welcome that information whether or not a notification is under review.

While I appreciate and respect the credibility of phytochemical analyses conducted by Dr. Khan and his colleagues at the National Center for Natural Products Research, I would point out that the phytochemical composition of a particular plant extract can legitimately vary based on the plant variety and method of cultivation and Pelargonium and Geranium are phylogenetically related genera that, between the two of them, contain several hundred species. Proving a negative, i.e. that no variety ever expressed methylhexeneamine, might be a challenge. On the other hand, if you are aware of efforts to falsify analytical data, we would be interested in discussing such information. More importantly, we would be interested in any information you have that demonstrates that methylhexaneamine or extracts of a botanical being sold as a dietary supplement are unsafe. We certainly remain available to discuss your concerns about supplement products containing this ingredient..

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Dan D. Levy, Ph.D.  
Microbiologist, Supervisor  
New Dietary Ingredient Review Team  
Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration  
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College Park, Maryland 20740  
301 436 2581 {tel.} {fax} 301 436 2636

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From: Amy Eichner, Ph.D. [mailto:AEichner@usada.org]

Sent: Wednesday, December 01, 2010 10:58 AM

To: Levy, Dan

Cc: Moore, Robert J

Subject: RE: NDI's

Hi Dr. Levy- I have a feeling someone will be submitting an NDI for methylhexaneamine- if they have not already done so. We have been amassing quite a bit of information about the history of this compound and have reason to argue that it should be regulated as a drug, not as a dietary ingredient. For starters we are investigating pelargonium extract ("geranium oil"). We find no evidence that methylhexaneamine is a natural constituent of this plant- there are about a dozen well designed studies where this compound is not found, and one obscure, non-peer-reviewed report from a PhD thesis from a third rate university in China that detected this compound. The study was very poorly designed. This is the study that Patrick Arnold cited when he trademarked "Geranamine".

We are conducting a "definitive" study by extracting the plant ourselves (with Ikhlas Khan at Ole Miss). While you may not be able to give me any details of pending notifications, could I at least discuss with you some of our considerations on this substance?

Best regards,

Amy

[cid:image001.jpg@01CB9181.6812EAB0]

[cid:image002.jpg@01CB9181.6812EAB0]

Amy Eichner Ph.D.

Drug References Resources Manager

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ATTENTION: Please notice our new address as of July 6th, 2010.

From: Moore, Robert J [mailto:Robert.Moore@fda.hhs.gov]

Sent: Tuesday, November 30, 2010 5:24 AM

To: Amy Eichner, Ph.D.

Cc: Levy, Dan; Spiller, Philip C

Subject: RE: NDI's

Dr. Eichner: Dr. Dan Levy is the Team Leader for the NDI Review Team. Bob \_\_\_\_\_

From: Amy Eichner, Ph.D. [mailto:AEichner@usada.org]

Sent: Monday, November 29, 2010 9:49 PM

To: Moore, Robert J

Subject: RE: NDI's

Hi Bob- Thanks so much for the info. We're a bit concerned about this issue here at USADA. Who at the FDA is in charge of NDIs? I'd like to know more about this process, and be sure that an NDI for methylhexaneamine doesn't go unscrutinized. We have reason to argue that methylhexaneamine in fact is NOT in geranium oil, and that methylhexaneamine should be regulated as a drug.

Kind regards,

Amy

From: Moore, Robert J [mailto:Robert.Moore@fda.hhs.gov]

Sent: Wednesday, October 13, 2010 10:36 AM

To: Amy Eichner, Ph.D.

Subject: RE: NDI's

Dr. Eichner: I've inserted some comments below.

bob

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From: Amy Eichner, Ph.D. [mailto:AEichner@usada.org]

Sent: Wednesday, October 13, 2010 11:55 AM

To: Moore, Robert J

Subject: RE: NDI's

Hello Dr. Moore-

Thank you so much for your thoughtful considerations on this matter. Your descriptions below help me to understand dietary ingredients and NDIs. I have just a couple of remaining questions.

- Can you give me some examples of plants that contain methylhexaneamine?

It is found in the oil of many geraniums - principally Pelargonium graveolens, the oil of which has a fairly long history of food use as an essential oil.

- If the source of methylhexaneamine in a dietary supplement is synthetic, is it still a dietary ingredient as described below?

This is a very complicated and legalistic issue. As a rule, FDA has generally taken the position that IF a substance is a "dietary ingredient" on the basis that it is a "constituent" of another dietary ingredient (for example, a plant), then it is a legitimate dietary ingredient only if it has been isolated from the other dietary ingredient. Thus, methylhexaneamine purified from geranium oil would be perfectly legitimate. However, if the substance is the synthetic version and was not isolated, then it would not be a legitimate dietary ingredient. There is a quite complex legal argument that forms the foundation of this tentative position - but in short, it boils down to something cannot be a "constituent" if it was never part of the whole.

However, there is an exception to this blanket prohibition of synthetic versions of naturally occurring ingredients. And that is the case where the synthetic substance is itself a dietary ingredient by virtue of it being a "dietary substance" within the meaning of section 201(ff)(1)(E) - that is, that the synthetic substance itself is a legitimate ingredient used in foods or dietary supplements. That means, if a synthetic version were to be an ingredient used in food or supplements in another country, then synthetic methylhexaneamine would become a legal dietary ingredient because it fits into the statutory definition of a dietary ingredient under section 201(ff)(1)(E) rather than 201(ff)(1)(F).

By the way, will you be attending Supply Side West? I see that Brad Williams will be speaking on the science behind botanicals. Perhaps I could also ask him a few botanical-related questions as well.

I will not be at Supply Side West - just Brad from our office is going.

Kind regards,

Amy

From: Moore, Robert J [mailto:Robert.Moore@fda.hhs.gov]

Sent: Wednesday, October 13, 2010 8:42 AM

To: Amy Eichner, Ph.D.

Cc: Coody, Gary

Subject: FW: NDI's

Dear Dr. Eichner:

The term "dietary supplement" is defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act) in section 201(ff) (21 U.S.C. 321(ff)). That section reads:

(ff) The term "dietary supplement"—

(1) means 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);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507

7<<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/FDCAActChaptersandShortTitleandDefinitions/ucm086297.htm#ftn7>>, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) 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, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act. Methylhexaneamine is found in many plants. Plants are dietary ingredients under section 201(ff)(1)(D).

Methylhexaneamine appears to be a "dietary ingredient" under section 201(ff)(1)(F) because it is a constituent of another dietary ingredient (i.e., a plant). Accordingly, if a product containing meets other applicable requirements of the FD&C Act, a firm could include this substance lawfully without FDA approval because there is no requirement for FDA review or approval of dietary supplements.

So-called "new dietary ingredients are defined in section 413 of the FD&C Act (21 U.S.C. 350b)). That section reads:

(a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt.

After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) PETITION.—Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.

(c) DEFINITION.—For purposes of this section, the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

The first question is whether the substance is a "new dietary ingredient." Therefore, if methylhexaneamine was not marketed as a dietary supplement before October 15, 1994 it would be a new dietary ingredient under section 413(c). The second question is whether a premarket notification is needed. If a dietary supplement containing meets the requirements in section 413(a)(1) above, then no notification is required. In practical terms, that section is an exemption from the notification requirement; if a firm could establish that the substance has a history of food/dietary supplement use (in the USA or elsewhere), then they would be able to market a dietary supplement containing it without prior notification of FDA or any premarket review by FDA. If there is no history of food use that satisfies the notification exemption provision, then the firm must submit a 75-day premarket notification to us pursuant to section 413(a)(2). To date, we have not received a notification for this substance from any firm.

There is no "list" of substances that are "new dietary ingredients" or that are not "new dietary ingredients." Neither is there a list of new dietary ingredients that are exempt from the notification requirement. At this time, FDA has reached no opinion as to whether products containing this substance violate the FD&C Act. But, the ingredient itself does appear to fit within the universe of "dietary ingredients" defined in section 201(ff)(1) of the FD&C Act.

If you have further questions or would like to discuss, please feel free to give me a call.

As far as new dietary ingredients go, all notifications we receive are filed in a public docket. That docket number is FDA-1995-S-0039 at

[www.regulations.gov](http://www.regulations.gov)<<http://www.regulations.gov><<http://www.regulations.gov><<http://www.regulations.gov>>>.

There is some general information on new dietary ingredients on our web site, but it doesn't go much beyond what I've described above: <http://www.fda.gov/Food/DietarySupplements/ucm109764.htm> (note: the NDI table on this web page is not current).

Sincerely yours,

Robert J. Moore, Ph.D.

Supervisor, Regulations Implementation Team Division of Dietary Supplement Programs (HFS-810) Office of Nutrition, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition US Food and Drug Administration  
5100 Paint Branch Parkway  
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From: Coody, Gary

Sent: Monday, October 11, 2010 7:46 PM

To: Moore, Robert J; Lewis, Kathleen

Cc: Miller, Elizabeth

Subject: FW: NDI's

Bob

Question from Amy Eichner at USADA about methylhexanamine, which is approved in foreign countries as a nasal decongestant with similar uses as phenylephrine (topical application). It is also naturally-occurring in germanium and other flower oils.

Eli Lilly studied it as a nasal decongestant but I don't know whether they applied to an IND.

. What is CFSAN's stance on this substance when used in a dietary supplement. I think this question has come up in the past.

Feel free to respond to Amy directly.

Thanks, Gary

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From: Amy Eichner, Ph.D. [<mailto:AEichner@usada.org>]

Sent: Monday, October 11, 2010 4:04 PM

To: Coody, Gary

Subject: NDI's

Hi Gary- We met at the UNPA Advertiser Beware seminar held last month, and I was wondering if you could tell me a little bit about NDI's and where I can get information about submitted or approved NDIs. Does the FDA maintain this information in a public forum or website?

We're interested because methylhexanamine is popping up in doping tests, so much so that WADA has made this a specified stimulant for 2011. This means that there is some discretion as to the sanction imposed on an athlete who tests positive for this substance. WADA does this for substances that are commonly consumed inadvertently.

Anyway, we'd just like to learn a bit more about its "legal" status, and the how and why it is ending up in dietary supplements or elsewhere in the food supply.

Thank you so much for your time, and I really appreciated your presentation at the UNPA seminar.

Kind regards,

Amy

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[[cid:image002.jpg@01CB9181.6812EAB0](#)]

Amy Eichner Ph.D.

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ATTENTION: Please notice our new address as of July 6th, 2010.

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