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Via Mail and Email

Re: "Body Building Products and Hidden Steroids: Enforcement Barriers"

Dear Ms. Wagner and Mr. Levy:

As president of the American Herbal Products Association, I listened carefully to Mr. Levy's testimony regarding Body Building Products and Hidden Steroids: Enforcement Barriers at the September 29, 2009 hearing before the Senate Committee on the Judiciary, Subcommittee on Crime and Drugs. The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry, and includes companies that manufacture and market botanical and other dietary supplements.

AHPA is concerned that the net impression left by Mr. Levy's testimony is that the FDA cannot presently take effective enforcement action with respect to synthetic steroids that are illegally marketed as dietary supplements. AHPA believes that FDA has all of the authority needed to act against any such product and is proposing by this letter that FDA adapt its current program for identifying, issuing Warning Letters, and informing the public

of fraudulent 2009 H1N1 influenza products as an efficient approach to identifying and initiating and publicizing enforcement actions against illegal synthetic steroid products.

More specifically, FDA should develop a three-part program to (1) search the Internet for marketed products labeled as containing synthetic steroid products; (2) send a Warning Letter to any company found to be marketing such product, the content of which should depend on the specific synthetic steroid ingredients described in the label, labeling or advertising of the product and the claims made for the product; and (3) prominently place on FDA's website a web page that lists products that the agency has identified as containing synthetic steroids and that have been the subject of Warning Letters. This is what FDA has done with products that make claims related to the 2009 H1N1 flu, and FDA could address illegal synthetic steroid products similarly, where the product is illegal for the simple reason that a claimed ingredient is illegal. And where a Warning Letter does not address the matter, FDA can look to criminal sanctions.

FDA's homepage now prominently displays its "FDA 2009 H1N1 Flu Page," which lists as its third topic "health fraud" where a link is provided to FDA's "Fraudulent 2009 H1N1 Influenza Products List."¹ Thus, within three clicks after arriving at FDA's homepage, consumers are informed of the identity of products, including air system products; body wash products; shampoos products; supplement products and many others, that the agency states are "illegally marketing unapproved, uncleared, or unauthorized products in relation to the 2009 H1N1 Flu Virus." FDA is apparently updating this page on a very regular basis so that consumers are informed of newly identified fraudulent products and can also find whether the complaints identified in FDA's Warning Letters to the marketers of these products have been addressed.² AHPA notes that the vast majority of the identified fraudulent claims have, in fact, now been resolved,³ and that this effort has therefore been an enforcement success.

Mr. Levy's testimony identified "several possible enforcement outcomes" when FDA determines that a substance in a marketed product as a steroid,⁴ depending on the

¹ <http://www.accessdata.fda.gov/scripts/h1n1flu/>; accessed October 3, 2009.

² In addition, FDA provides important disclaimers, so that consumers are also informed that the list provided "does not include every Web site that is marketing products related to the 2009 H1N1 Flu Virus without FDA approval, clearance, or authorization;" that even for unlisted Web sites "consumers should exercise caution before purchasing over the Internet any product purporting to diagnose, mitigate, prevent, treat, or cure the 2009 H1N1 Flu Virus;" that some of the listed products "may be approved or cleared by FDA for other medical uses;" and that FDA "has not determined whether these Web sites include products promoted for uses not related to the 2009 H1N1 Flu Virus that are also illegally marketed because they are not approved, cleared, or authorized by FDA for those other uses."

³ As of an update date of September 30, 2009 the site records that 120 of the 136 identified fraudulent products no longer bear unapproved, uncleared, or unauthorized claims on their websites.

⁴ Though this section of this testimony used just the word "steroid," it acknowledged elsewhere that there are "steroids [that] occur naturally in foods or are used as food ingredients and present no significant regulatory issues." AHPA therefore assumes that this section intended to describe possible enforcement outcomes when the agency encounters synthetic steroids in marketed products.

product's ingredients and marketing. This cited testimony identified three different combinations of product ingredients and marketing messages that would provide FDA with a clear path to enforcement.⁵ AHPA notes that Mr. Levy did not need to identify in his testimony a category of marketed synthetic steroids for which there is no possible enforcement outcome, because under current law, except with respect to approved new drugs, all such marketing is unlawful.

In conclusion, AHPA is suggesting here that FDA establish an approach based on the agency's very successful enforcement effort with respect to fraudulent H1N1 flu products. This program, including the issuance of Warning Letters and maintenance of the Fraudulent 2009 H1N1 Influenza Products web page, shows that aggressive enforcement action by FDA can stop false and misleading claims regarding products promptly and provide consumers with a list of bad actors and their products. As proposed by AHPA, athletes, parents, coaches, education officials, retailers, and those who seek to protect athletes from illegal steroid products, could also use FDA's website information to identify bad actors in this product area.

AHPA appreciates the efforts that you and your colleagues make to protect consumers from fraudulent products, and encourages you to seriously consider the course of action suggested here.

Sincerely,



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cc: Senator Arlen Specter
Senator Orrin Hatch
FDA Principal Deputy Commissioner Joshua Sharfstein

⁵ These three were described as: "First, if the steroid is the only active ingredient and the product is intended to affect the structure or function of the body, the product is an unapproved new drug. Second, if the product contains the steroid, in addition to one or more legitimate dietary ingredients (for example, herbal ingredients), the product would be an adulterated dietary supplement because it contains an unsafe food additive. Third, in rare instances, it may be determined that the steroid meets the definition of a dietary ingredient. In those instances, if the steroid is a new dietary ingredient for which a premarket notification is required, the product would still be an adulterated dietary supplement unless the manufacturer or distributor submitted a new dietary ingredient premarket notification to FDA at least 75 days before marketing."