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DIETARY SUPPLEMENT LEGAL UPDATE

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The dietary supplement industry continues to confront legal and regulatory challenges. Some recent significant developments are summarized below.

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FDA'S NEW DIETARY INGREDIENT GUIDANCE AND PATENTS

As Porzio previously reported, on August 11, 2016, the Food and Drug Administration (FDA) issued a revised draft guidance to improve dietary supplement companies' new dietary ingredient (NDI) premarket safety notifications to the agency. The NDI Guidance raises issues for companies seeking to protect their intellectual property rights, particularly patents and trade secrets.

The Dietary Supplement Health and Education Act (DSHEA) requires the manufacturer or distributor to notify the FDA at least 75 days before beginning to market a dietary supplement that contains a "new dietary ingredient," which is defined as one that was not used in the food supply and marketed in the United States before October 15, 1994. Supplements are considered adulterated if they contain an NDI not used in the food supply and the required notification has not been submitted to the FDA 75 days before marketing. The draft Guidance is available at Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.

The Guidance presents challenges for companies that have applied for or obtained patent protection on their supplement product. Patents are available for inventions that are novel and non-obvious. A supplement cannot be patented if it was previously patented, described in a printed publication, or is in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

In This Issue

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For patent applications for a dietary ingredient filed prior to October 15, 1994, the dietary ingredients are grandfathered in and are not NDIs. However, any issued patents have likely expired. Patent applications filed prior to June 8, 1995 have a term measured by the longer of 17 years from the issue date of a patent or 20 years from the date of filing.

For patent applications filed after October 15, 1994, however, the NDI Guidance has the potential to directly affect patentability and regulatory compliance. If a company takes the position that an ingredient was in the diet before October 15, 1994, it would avoid regulatory issues because it would not be considered a NDI and there is no need to submit a NDI Notification (NDIN) to FDA. The company, however, may not be able to obtain a patent because the ingredient was "in use" or "on sale" before the priority date claimed by the inventor. But if the company takes the position that the ingredient was not in the diet before October 15, 1994, it could be protected by a patent. It might, however, need to submit a NDIN, subjecting the ingredient to regulatory issues and possible rejection by FDA. This interplay of patent and regulatory questions requires careful and strategic consideration.

FDA ISSUES FINAL GRAS RULE ON FOOD INGREDIENTS

On August 12, 2016, FDA finalized its proposed rule on substances generally recognized as safe (GRAS). It describes the required criteria and scientific evidence that can be used to demonstrate that the use of a substance in human or animal food has GRAS status. The final rule replaces a voluntary GRAS notification procedure used since 2010. Under the final rule, FDA must respond to a GRAS notice filing within 180 days (which may be extended for an additional 90 days).

The rule provides that a substance cannot be classified as GRAS under the conditions of its intended use if the available data and information do not satisfy the safety standard for a food additive under the Food Drug and Cosmetics Act. GRAS requires "common knowledge," throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food, that there is a reasonable certainty that the substance is not harmful. "Common knowledge" can be based on either "scientific procedures" or on experience based on common use of a substance in food prior to January 1, 1958. General recognition of safety through scientific procedures must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

The final rule is published at Substances Generally Recognized as Safe.

FDA QUESTIONS STATUS OF VINPOCETINE AS A DIETARY SUPPLEMENT

FDA has asked for comment on whether Vinpocetine, widely marketed for improved memory, can be sold as a dietary supplement. In a request for comment, FDA wrote that Vinpocetine is a synthetic compound, derived from vincamine, an alkaloid found in the Vinca minor plant, or tabersonine, an alkaloid found in Voacanga seeds. The FDA believes that Vinpocetine does not fall within the

definition of "dietary supplement" in the 1994 Dietary Supplement and Health Education Act because it is not a vitamin, mineral, herb or other botanical, or a concentrate, metabolite, constituent, extract, or combination of any such ingredient. The FDA further indicated that Vinpocetine does not qualify as a dietary supplement because it was approved for investigation as a new drug in 1981, substantial clinical investigation of the product had begun, and the existence of the investigation had been publicized.

FDA's position is controversial because Vinpocetine was the subject of five notifications as a new dietary ingredient, going back to 1997. FDA did not object to any of the notifications or the subsequent sale of Vinpocetine as a dietary supplement. Industry invested in the product in reliance on the notifications. If FDA maintains its position, Vinpocetine could no longer be sold.

FDA has requested comments on Vinpocetine by November 7, 2016. A copy of FDA's request for comments is at Request for Comment on the Status of Vinpocetine.

DEA LISTS KRATOM AS A CONTROLLED SUBSTANCE

On August 30, 2016, the Drug Enforcement Administration (DEA) announced it would list the active materials in the kratom plant as a drug under Schedule I of the Controlled Substances Act. Mitragynine and 7-hydroxymitragynine are found in kratom, which is a tropical tree. The DEA said that Kratom produces opioid-like effects and is often marketed as a legal alternative to controlled substances. In addition, it concluded that kratom has a high potential for abuse and is not accepted for safe medical use. The DEA's notice is available at Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I.