



September 26, 2025

Navneet Sharma  
Chief of Quality & Regulatory Affairs  
IGY Immune Technologies and Life Sciences, Inc.  
4 East Lake Avenue 1A  
Calgary, Alberta T4A 2G8  
Canada

Dear Navneet Sharma:

This letter responds to the notification that you submitted, pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), to the Food and Drug Administration (FDA or we). FDA received and filed the notification on July 23, 2025. Additional information was received on August 4 and 20, 2025, and September 4 and 17, 2025. Your notification concerns the new dietary ingredient, “Muno-IgY”, that you intend to market as a bulk dietary ingredient under the trade name “Muno-IgY™”.

According to your amended notification, the conditions of use are that a maximum serving size is two servings of Muno-IgY at 50 mg/serving with 8 hours between servings for a total of 100 mg/day for chronic daily use (providing up to 45 mg/day IgY); better to take on an empty stomach. Target Population(s): Healthy adults. Excluded Population(s): Not intended for use by children or pregnant or lactating women. The NDI will also include an allergen alert - contains egg.

Under 21 U.S.C. § 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. § 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the condition recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. § 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

In accordance with 21 CFR 190.6 (c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification. Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. § 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of July 23, 2025. After the 90-day date, the notification will be placed on public display at [www.regulations.gov](http://www.regulations.gov) as new dietary ingredient notification report number 1424. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and include an explanation of the basis for this belief.

If you have any questions concerning this matter, please contact Markeesa Scales, MPH, Division of Research and Evaluation by email: [NDITEAM@fda.hhs.gov](mailto:NDITEAM@fda.hhs.gov).

Sincerely,

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Date: 2025.09.26 12:24:10 -04'00'

R. Philip Yeager, PhD, JD, DABT  
Director  
Division of Research and Evaluation  
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