

Excellent Pharma Consulting, Inc

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Office of Food Additive Safety (HFS-200)

Sept 4, 2024

Center for Food Safety and Applied Nutrition

United States Food and Drug Administration

5001 Campus Drive

College Park, MD 20740

RE: Affirmation of GRAS Status of HyON Water™

To Whom it Concerns:

As the registered agent, Excellent Pharma Consultants, Inc., we are writing to inform you that our product, HyON Water™, does not require a reapplication for Generally Recognized as Safe (GRAS) status application. While notifying the FDA is not required, we believe it is helpful for the FDA in monitoring the safety of ingredients more effectively.

Our rationale is based on the following key points.

1. Per 21 CFR 170.3, if an ingredient (GRN 480) already has GRAS status for a *specific use*, and there are *no changes in the production process, intended use, or new safety information*, it is not necessary to reapply for GRAS status.
 - a. GRN 480 for sulfuric acid blend is recognized as GRAS as an acidifier and antimicrobial.
 - b. The safety of these ingredients for such uses as an acidifier and antimicrobial has been well-established and is supported by scientific evidence as required by the FDA. The safety of HyON Water™ is based upon the fact that the finished product is only comprised of water (with an increase of charged hydrogen ions) and trace levels of sulfates. The only ingredient used with high quality pharmaceutical grade water is sulfuric acid (CAS Reg No. 7664-93-9) which is used as a pH adjustor and is listed and affirmed GRAS by the FDA (GRN No. 408). The sulfuric acid used is listed under 21 CFR §1784.1095 for use as a pH control agent and as a processing aid. The sulfuric acid is also permitted for use as an indirect food additive and used as a component of paper and paperboard in contact with both dry food (21 CFR 176.80) and fatty foods (21 CFR 176.170).
 - c. The production process has the same ingredients (same starting concentration of sulfuric acid) added to water to achieve an aqueous solution of diluted sulfuric acid, with the purpose of adjusting the solution pH (acidifier). The production process varies slightly (concentrated sulfuric acid diluted with water versus diluting concentrated sulfuric acid then adding anhydrous sodium sulfate crystals).

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- d. The intended use as an acidifier and antimicrobial agent aligns with the FDA recognized uses of its ingredients.
- e. Pursuant to 21 CFR §§ 170.30 (a) and (b) HyON Water™ is manufactured in accordance with 21 CFR Part 201-211, current Good Manufacturing Procedures (cGMPs)¹.

Therefore, pursuant to 21 CFR §§ 170.30 (a) and (b) HyON Water™ is affirmed GRAS for its intended use as an acidifier and antimicrobial² agent that is manufactured in accordance with 21 CFR Part 201-211, current Good Manufacturing Procedures (cGMPs)

HyON Water™ is a proprietary formulation intended as an antimicrobial agent that is manufactured in accordance with 21 CFR 201-211, current Good Manufacturing Procedures (cGMP). The safety of the product is based upon the fact that the finished product is only comprised of water (with an increase of charged hydronium ions) and trace level of sulfates. This final formulation meets the EPA Safe Drinking Standard.

The only ingredient used with high quality pharmaceutical grade water is sulfuric acid (CAS Reg No. 7664-93-9), used as an acidifier and affirmed GRAS by the FDA (GRN No. 480). Water is GRAS for use in food but does not have a specific GRAS number because it is a fundamental and ubiquitous substance in food production. Sulfuric acid is listed as GRAS under 21 CFR 184.1095, particularly as an acidifier for pH control and as a processing aid.

Previous products using sulfuric acid and sodium sulfate, as well as other blends with sulfuric acid are recognized as GRAS (e.g., GRN 480 lists sulfuric acid as an acidifier and antimicrobial).

During a previous meeting with the FDA to discuss our product, it was presented that the two-ingredient formulation, consisting of water and sulfuric acid, had no detectable levels of sulfuric acid in the final product. Despite this, the FDA specified that the application be adjusted to add a new use of sulfuric acid as an antimicrobial. To address their concerns preparation of a new GRAS summary was initiated and we discovered that sulfuric acid used in HyON Water™ is already recognized as GRAS when used as an acidifier and antimicrobial.

Thank you for your consideration. A response would be appreciated.

Respectfully,

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¹ Good manufacturing practices (GMP) provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. The main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and that the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS). A key feature in this document is the use of the minimum amount to accomplish the intended technical effect.

² Antimicrobial agent for HyONUS, Inc. products is defined as an agent effective against vegetative bacteria, yeasts and molds, sporicidal, and anti-viral agent.