

Date 3-4-19

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane rm. 1061
Rockville, MD 20852

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MAR 12 '19 AM 11:41

CITIZEN PETITION

The undersigned Don Buel submits this petition under 21 CFR 10.30, of the (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to exempt a regulation or refrain from taking any other form of administrative action).

A. Action requested

Independent Nutrition (INC) is requesting an exemption, under 21 CFR 10.30, to the testing requirements listed in 21 CFR 111.75 (a)(1)(i), which states (a) Before you use a component, you must: (1)(i) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, unless you petition the agency under paragraph (a)(1)(ii) of this section and the agency exempts you from such testing.

Independent Nutrition Inc. (INC) is requesting the commissioner take action that allows Independent Nutrition Inc. to accept the organic certificate from the USDA for the identity of herbs and herbal extracts used in the production of dietary supplement products. We are asking that the FDA accept the identity process for organic herbs and herbal extracts that the USDA certifies as organic. Therefore Independent Nutrition Inc. would not have to do more identity testing upon receiving these raw materials that have been organically certified by USDA. The organic certificate would satisfy section 111.75 (a)(1)(i) and would be in place of conducting a test or examination to verify the identity of herbs and herbal extracts used in Independent Nutrition products. The organic certificate submitted by the vendor is verified on the USDA Organic Integrity Database Website.

B. Statement of grounds

The USDA requires in-depth reporting in obtaining an organic status for herbs and herbal extracts. From the "Documentation Forms for Organic Crop Producers" the following pages are included for organic crop producers and must be submitted. These pages include all aspects of the plant from seed to harvest. The organic grower must document field history/previous land use, land use history verification, activity log, activity calendar, planting and harvest record, crop rotation record, input material application record, compost production record, manure

application/food crop harvest interval record, seed records part A (suppliers of seed or planting stock), seed record part B (nonorganic seed or planting stock), seed record C (documentation of allowability of seed treatments, coatings, or inoculants), seed saving and planting stock propagation record, harvest record, farmers market load list or fam stand sales record, harvest plan and record “pick list”, CSA weekly harvest and cost summary, harvest instructions, total farm sales record, storage inventory record, equipment cleaning log, clean transport affidavit, buffer crop disposition records, sample neighbor notification letter and adjoining land use verification. Some of these steps require third party verification for the application (e.g. organic status of input material is verified by a certified agency) and sometimes verification is requested if the USDA determines it needs to verify self –reported information. Normally an on-site inspection is done for verification. The three seed record pages of information are what are important for plant identification. From the “Documentation Forms for Organic Crop Producers” pages C10-C13 include the seed records of the names and contact information of seed and planting stock suppliers who handle organic seeds and stock and information on allowability of seed treatments and seed saving and planting stock propagation.

For the purpose of this petition it is the seed verification, and the records that go with this, which indicates the identity of the herb that USDA verifies. This method of plant identification would replace Independent Nutrition from having to test the herb upon receiving the material into our facility. In this case the USDA is validating the herb or herbal extracts identity and further testing would be a duplication and more costly. We believe the FDA should recognize USDA results.

In Guidance document NOP 5029 “Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production” details of plant seed identification and other requirements are described. The guidance describes practices for certified operations to demonstrate their proactive efforts to procure all organic seeds, annual seedlings, and planting stock in support of their organic system plan (OSP). The producer must keep detailed records of all seed and planting stock.

The role of the certifying agent is to verify the commercial availability of organic seeds and transplant stock and verify the procedures that certified operations utilize to obtain and plant organic varieties. An on-site inspection is done by the certifying agent at each production unit. Refer to 7 CFR 205.402-205.405. The National Organic Program (NOP) is very thorough in verifying the identity of plants grown that are organic certified.

Lastly, there are programs, mostly through extension offices, that provide seed quality genetic purity assessments as well as other seed quality attributes. There are state agencies that can certify seed once it has passed the field inspection and the laboratory analysis. These agencies are available to the independent specialty seed companies; however this system has not typically been used by smaller, independent specialty seed companies which mostly have their

own internal quality control systems. The list of state testing and certification resources is included in the attachments.

Like any other industry that relies on another agency for certification there are companies that will falsely report their products as organic. It is INC's responsible, as the purchaser of these organic herbs and herbal extracts, to validate that when a company reports a material as organic that the organic status is confirmed. There are various means to do this with the main one being the FDA Organic Integrity website. We believe USDA is a trustworthy agency.

Small businesses produce and sell 38% of the dietary supplements¹ in the market place. This is compared to 44% from conventional retailers (i.e. Walmart, Amazon) and therefore small companies have a greater need to keep costs under control while still being able to provide safe and affordable products. INC needs to take advantage of processes that streamline the testing process without sacrificing quality. In this case the USDA is validating the herb or herbal extracts identity and further testing to satisfy FDA would be duplication of tests and create un-necessary costs.

Independent Nutrition Inc. is requesting the commissioner take action to allow Independent Nutrition Inc. to accept the organic certificate from the USDA for the identity of herbs and herbal extracts used in the production of dietary supplement products. We are asking that the FDA accept the identity process for organic herbs and herbal extracts that the USDA has certified as organic. Therefore Independent Nutrition Inc. would not have to do more identity testing upon receiving these raw materials that have been organically certified by USDA.

¹ NFM-Natural Foods Merchandiser July/August 2018 Vol 39.04

C. Environmental impact

Claim for categorical exclusion under §§25.30 (h) and (j).

D. Economic impact

Only if requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and view on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Don Buel

Independent Nutrition

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Attachments

21 CFR 111.75 (a)(1)(i)

Guidance NOP 5029

7 CFR 205.402-205.405

USDA Documentation Forms for Organic Crop Producers

Extension Seed Quality Testing and Certification: Resources Useful in Organic Seed Production

Protecting Organic Seed Integrity: <http://www.osgata.org/organic-seed-integrity/>

References

1. USDA National Organic Program Regulations:

https://www.nofany.org/files/NOP_Organic_Regulations.10.26.15.pdf

2. Protecting Organic Seed Integrity: <http://www.osgata.org/organic-seed-integrity/>

cc National Product Association (NPA)

cc American Herbal Products Association (AHPA)

cc Mountain Rose Herbs

cc Senator Ron Wyden

cc Senator Jeff Merkley

cc House congressman Peter DeFazio

Eugene OR 97402
541-954-2520

¹ NFM-Natural Foods Merchandiser July/August 2018 Vol 39.04

Attachments

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cc American Herbal Products Association (AHPA)
cc Mountain Rose Herbs
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cc Senator Jeff Merkley
cc House congressman Peter DeFazio

FROM: (541) 345-5846
DON BUEL
INDEPENDENT NUTRITION CENTERS
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EUGENE OR 97402
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SHIP DATE: 04MAR19
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BILL SENDER

551CL/4603/104C

TO DIVISION OF DOCKETS MANAGEMENT FDA
FOOD AND DRUG MANAGEMENT HHS
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