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

CITIZEN PETITION

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The undersigned

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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

1

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 through 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

2

**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.

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Don Buet

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

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Eugene **OR** 97402 541-954-2520

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

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

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FROM:

DON BUEL

(541) 345-5846

INDEPENDENT NUTRITION CENTERS

4091 W 11TH AVE

EUGENE OR 97402

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ΤΟ **DIVISION OF DOCKETS MANAGEMENT FDA**

**FOOD AND DRUG MANAGEMENT HHS**

**5630 FISHERS LANE ROOM 1061**

**ROCKVILLE MD 20852**

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