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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2018–N–4042 for "*Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products*" (Publication Date: January 14, 2019)

Dear FDA Desk Officer:

The Natural Products Association (NPA) is submitting this letter as general comment to docket FDA–2018–N–4041 (Docket Name: Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products). The NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products, including conventional foods, medical foods, dietary supplements, and foods for special dietary use. The NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,100 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of

natural products, including foods, dietary supplements, homeopathic products, and health/beauty aids. Many of our manufacturing/distribution/retail members sell and export Center for Food Safety and Applied Nutrition (CFSAN)-regulated products overseas, and therefore NPA has an interest to submit comments on this topic. Thank you for the opportunity to comment.

Background

On November 13, 2018, FDA announced an opportunity for public comment on the proposed collection of certain information by the Agency. This notice solicits comments on the collection of information that FDA uses to establish and maintain lists of U.S. manufacturers and processors with an interest in exporting products regulated by CFSAN to countries that require such lists to be maintained. The notice solicits comments on changes to the electronic registry that will allow manufacturers and processors of CFSAN-regulated products to electronically request inclusion on the export lists. FDA invites comment on 1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; 2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; 3) ways to enhance the quality, utility, and clarity of the information to be collected; and 4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Should Provide a List of Countries Who Require and Utilize These Lists Along with Their Purpose

It is not altogether clear what countries are asking FDA for these lists of U.S. companies and for what purpose. FDA states that it "*currently maintains export lists for the European Community and China covered under OMB control numbers 0910-0320 and 0910-0839, respectively … to assist firms to meet the import requirements of foreign governments*." Out of transparency, NPA requests FDA to openly provide a list of countries in the European Community requesting this information. It is our guess that not all European nations require this information, and U.S. companies have a right to know, out of transparency, which countries are asking for this list and which ones are not. NPA would also like to know what other information FDA is sharing in its own databases with foreign governments. U.S. companies have a right to know what information is being communicated to foreign entities as it relates to administrative actions (e.g. warning letter), inspection outcomes (NAI, VAI or OAI status) from FDA's Compliance Management System (CMS), or enforcement actions (e.g. injunction or seizure). If FDA is requesting information of U.S. companies then it also needs to publish which countries are requesting it and to notify U.S. companies when it plans on notifying those foreign governments with an updated list. FDA should also disclose the information it is sending to foreign governments to those U.S. companies.

FDA Requests Information to Be Included in Lists for Foreign Governments but That Information Is Already in FDA's Possession

Several areas of information FDA requests from U.S. companies is already in FDA's possession. For example, why is FDA asking for information about the Food Facility Registration number, the agencies that inspected the plant/facility, the date of last inspection, plant/facility number, and copy of last inspection notice? This is information already contained in FDA

databases. Asking for the same information is a waste of time for U.S. manufacturers. FDA states that it considers information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4); however, much of the information FDA requests for the list is information FDA already has in its possession. Why is FDA requesting information it already has in its own possession? FDA should know when a firm was last inspected by FDA, for what purpose (e.g. for cause inspection, routine conventional food inspection under part 110, routine dietary supplement inspection under part 111, routine drug inspection), and the disposition of that inspection (NAI, VAI, OAI). FDA has an entire database (e.g. CMS) dedicated to this information. It should not have to request this information. Similarly, FDA should have knowledge of food facility registration numbers for firms as per the Registration of Food Facilities requirement under the Bioterrorism Act of 2002. It seems that if FDA has taken up the task to determine eligibility of companies for foreign lists, it should not shift such a burden back on U.S. industry when it already has this information in its databases. FDA should be able to populate the list with information from CMS and other databases like its Federal Food Registry to inform foreign governments that a U.S. company has been in compliance with all federal regulations and should be deemed eligible for inclusion on FDA's list to foreign governments.

Why Is FDA Involved in Determining the Requirements of An Importing Country and Evaluating Third-Party Certification Documents Toward Eligibility for List Inclusion?

FDA follows a different code than foreign governments as to what is acceptable and compliant for imports and exports. FDA's federal code is codified in title 21 of the Code of Federal Regulations. FDA seems to now be engaging in activities to determine what company is acceptable or eligible for inclusion in a list to foreign governments and serving as a repository for that information. That is not the mission of the U.S. FDA. FDA writes that "*[i]n addition to the information described above, FDA states that some countries may require additional information*

such as documentation that the firm has been certified by a third-party certification body that it meets the requirements of the importing country." NPA requests FDA release the documents and requests submitted to the Agency from each foreign government entity as to new implementing requirements for that importing country. Furthermore, there are numerous third-parties performing certifications for foods and dietary supplements. FDA should provide a list as to what third-party certifying bodies and certification programs each foreign government is looking for as well as FDA's criteria for what it determines to be an eligible third-party certification that can be used toward inclusion of a company's name in a list for foreign governments.

Under What Authority Can FDA Provide An "*Eligibility Screening Service*" For Foreign Governments?

While FDA believes they are providing help to U.S. companies, FDA appears to be providing what amounts to an "*eligibility screening service*" for foreign governments as well as housing a repository of this information submitted to it by U.S. companies. NPA asks under what authority does FDA have to provide this service to foreign governments? FDA further states that *"[o]ther information may need to be submitted to be included on the lists depending on the requirements of the importing country*." When will FDA share what information may be required next and from what foreign government? Does FDA plan on releasing this information soon? FDA operates within the sovereign laws of the United States. It is unclear to NPA how FDA can be asked by foreign governments to provide this sort of service and determine whether a U.S. company is eligible to be included on this list. What is FDA looking for in a third-party certification document to determine whether it satisfies FDA's criteria for eligibility? Does FDA have guidance for industry on what will be deemed acceptable in a third-party certification toward meeting the requirements for inclusion on the list for foreign governments? There are many third-party certifications and several third-party certifying bodies providing those certifications. It would be

more helpful to industry if it publishes what each country is looking for in third-party certifications. Is FDA going to release how it plans to provide exporters with this information as well as about any additional information required by a foreign country as a condition for entry and to accommodate the importing countries' requirements? How will FDA collect that additional information?

FDA Needs to Publish the Eligibility Requirements for Each Country

FDA states that they "*use the information submitted by firms to determine their eligibility for placement on the export lists, which may be published on our website*." Once NPA can understand how FDA has authority to determine eligibility of a U.S. company for placement on an export list based upon foreign government requirements, then we can proceed to how FDA will publicly inform U.S. industry of the eligibility requirements for each country. NPA believes this is a necessary requirement for transparency in U.S. exports to foreign countries.

How Can FDA Ask for Company Name, Address and Food Registry Information and Disclose to Foreign Countries, But It Refuses to Disclose the Same Information Submitted to It Under the Bioterrorism Act Of 2002?

NPA is trying to understand why it is unable to receive information from FDA databases about who has submitted food registry information under the Bioterrorism Act of 2002. FDA is asking companies to submit the same information here (e.g. name/address of the exporting U.S. company and food registry information) to it again for the purposes of sharing with foreign countries so that a company can export products. This appears that FDA is catering to the wishes and demands imposed on it from foreign governments while being less than transparent with

non-government organizations (NGOs), associations, other stakeholders, and the public within the U.S.

Conclusion

The NPA thanks FDA for this opportunity to comment, and we look forward to participating in this important regulatory process of public notice and comment in the future as FDA publishes its eligibility requirements to make it on these lists for foreign governments. NPA hopes FDA will consider the suggestions, and changes offered up in these comments.

Respectfully submitted,

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