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MEMORANDUM

From: Joseph A. Levitt
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Re: **FDA Seeks Comments to Identify Regulations for Modification, Repeal, or Replacement**

The U.S. Food and Drug Administration (FDA) has issued a broad request for comment to assist the agency in identifying regulations and related paperwork requirements that it could modify, repeal, or replace to reduce the regulatory burden on the public. 1/ The request is specific to products within the jurisdiction of the Center for Food Safety and Applied Nutrition (CFSAN) (i.e., human food, dietary supplements, and cosmetics) and presents a unique opportunity for industry to identify regulations and/or information collection (paperwork) requirements that are outdated, ineffective, or unnecessary; impose costs greater than their associated benefits; or limit job creation.

FDA issued the request as part of its implementation of Executive Orders (EOs) 13771 and 13777. EO 13771, entitled "Reducing Regulation and Controlling Regulatory Costs," states that it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds from both public and private sources and to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations. EO 13777, entitled "Enforcing the Regulatory Reform Agenda," directs each agency to establish a Regulatory Reform Task Force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. The information the public submits in response to the request for comment will supplement FDA's review of its regulations. This memorandum summarizes FDA's requests and the specified formatting and instructions for providing comments.

Specific Information Requests

Though the public may submit information on other issues, FDA's request includes the following questions, which the agency is using to guide its review of regulations to identify those it could modify, repeal, or replace to reduce the regulatory burden on the public:

- Is the regulation still current, or is it outdated or unnecessary in some way?
    - Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

1/ Review of Existing Center for Food Safety and Applied Nutrition Regulatory Information Collection Requirements, 82 Fed. Reg. 42503 (Sept. 8, 2017).

- Has the regulation been superseded or made irrelevant or unenforceable by statute, another FDA regulation or guidance, a regulation by another Federal Agency, or controlling legal authority? If yes, identify the statute, regulation, guidance, or legal precedent and explain what FDA regulation is affected and in what way it is affected.

- Is this regulation duplicative of requirements in other FDA regulations or other Federal Agency regulations? If yes, identify the overlapping regulation(s) and responsible Federal Agency and describe the way(s) in which the regulations overlap, as well as any suggestions with respect to how best to resolve the duplication.

- Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.

- Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third party organizations (e.g., International Council for Harmonisation, International Organization for Standardization, Codex Alimentarius)? Do the entities covered by these standards or guidance take steps to meet the standards and to document that they meet the standards? If met, do the standards achieve the same level of public health protection as the FDA regulation? Are there entities who are not covered by these standards or guidances or who choose not to observe them?

- Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g., reporting, recordkeeping, or labeling requirements? Explain in your response why the information is redundant, outdated, or unnecessary.

- Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

- What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

FDA requests that comments be as specific as possible and included any supporting data or information, such as cost information and *Code of Federal Regulations* (CFR) citations, when applicable. FDA also urges commenters to provide a specific suggestion regarding whether a regulation should be repealed, replaced, or modified. Note especially that if commenters suggest a modification, FDA asks that they provide the specific text they recommend.

Instructions and Formatting for Comment Submissions

Comments may be submitted either electronically or in paper form, unless the comments contain confidential information. Comments containing confidential information must be submitted only in hard copy. One copy should be un-redacted and contain the heading "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION," and the second copy should have the confidential information redacted. FDA will make the second copy available on www.regulations.gov. We encourage a careful review of the full submission instructions, as all documents submitted electronically will be made available to the public without any review for confidential information.

To allow the agency to more efficiently review comments, FDA also requests that comments be submitted using the following format:

Name of regulation		
Type of product or FDA Center regulating the product.		
Citation to *Code of Federal Regulations* and statutory citation (as applicable).		
Approved information collection and OMB Control Number (as applicable).		
Brief description of concern		(For example, what innovation makes the regulation outdated? Why?)
Available data on cost or economic impact		(Quantified costs and/or costs savings. Qualitative description, if needed.)
Proposed solution		(Include your solution. For example, how would you modify the regulation? Provide specific text if you are recommending a modification.)

All comments must include the Docket Number FDA-2017-N-5094 for "Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements." Comments are due on December 7, 2017. FDA states that late, untimely filed comments will not be considered.

The request for comment is a unique opportunity for industry to identify regulations that are outdated, ineffective, or unnecessary; impose costs greater than their associated benefits; or limit job creation. We encourage industry to submit recommendations for ways in which FDA could make its regulations less burdensome while still achieving the agency's public health mission and statutory obligations. We would be happy to assist clients in preparing such comments.

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We will continue to monitor the implementation of the Trump administration's regulatory reform agenda. Please do not hesitate to contact us if you have any questions regarding this or any other matter.