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MEMORANDUM

From: Joseph A. Levitt
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Re: **DOJ Memoranda Limit the Use of Guidance Documents in Civil Actions**

As seen in news reports, two recent Department of Justice (DOJ or Department) memoranda address the role of guidance documents in civil enforcement actions. Taken together, the two memoranda greatly limit the Department's use of DOJ and other agencies' guidance documents to support civil enforcement actions, as guidance documents do not impose binding standards on private parties. However, for the reasons set forth below, the memoranda are not expected to have a significant impact on enforcement actions initiated by the Food and Drug Administration (FDA) in food-related matters.

The first such memorandum was issued on November 16, 2017, when Attorney General Jeff Sessions issued a DOJ memorandum stating that the DOJ will no longer bring civil cases on the basis of failure to comply with a DOJ-issued guidance document. 1/

The justification for this position is largely based on the desire for the DOJ to "model the lawful exercise of regulatory power" when engaging in regulatory actions. The memorandum cites the Administrative Procedure Act (APA) as generally requiring notice-and-comment rulemaking in instances when rights or obligations are created and become binding on the public. The memorandum states that the DOJ will no longer use Department guidance documents (or similar instruments) to bind private parties, as guidance foregoes the rulemaking process, and the rulemaking process "results in better decisions by regulators."

The memorandum notes that DOJ guidance may still be utilized in civil enforcement actions if its purpose is to educate regulated parties or guide the application of laws and regulations. This type of guidance merely provides plain language explanations of legal requirements, or gives examples or practices that help parties to interpret obligations. However, under the memorandum, DOJ will no longer issue guidance that imposes new requirements or binding standards on private parties, through which the DOJ determines compliance with statutory or regulatory requirements. The

1/ The Attorney General's DOJ memorandum is available at https://www.justice.gov/opa/press-release/file/1012271/download.

memorandum states this is effectively "substitute rulemaking," and is not permissible under the APA. As a result, the DOJ will no longer engage in issuing this kind of guidance, and it will work to repeal, replace, or modify any current DOJ guidance that creates such binding standards.

In order to avoid any circumventing of the rulemaking process, the memorandum cites five principles that DOJ will follow in issuing its own guidance documents:

- Guidance documents should identify themselves as guidance, disclaim any force or effect of law, and avoid language suggesting that the public has obligations that go beyond those set forth in the applicable statutes or legislative rules.
- Guidance documents should clearly state that they are not final agency actions, have no legally binding effect on persons or entities outside the federal government, and may be rescinded or modified in the Department's complete discretion.
- Guidance documents should not be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation.
- Guidance documents should not use mandatory language such as "shall," "must," "required," or "requirement" to direct parties outside the federal government to take or refrain from taking action, except when restating—with citations to statutes, regulations, or binding judicial precedent—clear mandates contained in a statute or regulation. In all cases, guidance documents should clearly identify the underlying law that they are explaining.
- To the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action.

It is clear that this memorandum applies to guidance documents issued by the DOJ, but the guidance documents issued by other agencies were not discussed. However, more recently, on January 25, 2018, Associate Attorney General Rachel Brand expanded the scope of this DOJ policy with the issuance of a second DOJ memorandum. 2/ This second memorandum states that the principles from the DOJ's new policy on guidance should guide Department litigators "in determining the legal relevance of other agencies' guidance documents in affirmative civil enforcement." This makes it clear that the Administration will seek to apply these same principles to guidance developed by other agencies, such as the FDA, in its civil enforcement actions.

Nevertheless, these memoranda are not expected to have any major impact on FDA-initiated enforcement actions. Note, for example, that under FDA's Good Guidance Practice regulations 3/, the FDA already states very clearly in all of its guidance documents that they are not legally binding and do not impose new legal requirements. Moreover, most agency Warning Letters or civil enforcement actions cite to the FDA law and regulations as the basis for the government's action.

Where the memoranda may be more useful to the food industry would be two-fold: either (1) in commenting on draft guidance documents, to the extent the drafts are viewed as arguably going beyond the scope of existing law and regulations; or (2) pushing back during FDA inspections if the

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2/ The Associate Attorney General's DOJ memorandum is available at https://www.justice.gov/file/1028756/download.

3/ *See* 21 CFR 10.115.

company perceives that the investigator is seeking to “enforce” an existing guidance document in a manner that is beyond the scope of the regulations. Companies are encouraged to consult with legal counsel should either of these two circumstances occur.

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We will continue to monitor any changes in FDA regulation and enforcement that may result from the DOJ memoranda. Please contact us with any questions.