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MEMORANDUM

From: Joseph A. Levitt
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Re: **FDA Proposes New Rule to Increase Transparency and Access to Agency Documents Under FOIA**

The Food and Drug Administration ("FDA" or "the agency") recently issued a proposed rule that will ease the Freedom of Information Act ("FOIA") request process for certain records within FDA's possession. 1/ The proposed rule would amend FDA's regulations to reflect updated Federal requirements for information access, clarify certain provisions of FDA's information access regulations, and make the FOIA process easier for the public to navigate. The agency anticipates that these changes, taken together, will enhance transparency for the public with regard to FDA activities.

FOIA is a law that gives the public the right to access information from the Federal government. There is a presumption that government records must be released under FOIA unless they are subject to an exemption. In this regard, FDA is proposing to amend its regulations to state explicitly that the agency would withhold information under FOIA only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law.

Under the most notable of the proposed amendments, FDA would be required to make available for public inspection in an electronic format records that have been requested three or more times under FOIA. The same would apply to records that have been released to any person in response to a FOIA request for which the agency has determined "have become, or are likely to become, the subject of subsequent requests for substantially the same records." FDA explains that "[t]his change codifies the long-standing Department of Justice policy of federal agencies posting records that have been requested three or more times" and that "this change is to proactively release records to the public without the need for submission of additional FOIA requests." 2/ FDA explains it has been informally operating under this Department of Justice policy as a part of its standard practice in responding to FOIA requests; however, the proposed rule would amend FDA's regulations in 21 C.F.R. Part 20 to reflect this practice.

1/ 83 Fed. Reg. 46437 (September 13, 2018), *available at* https://www.gpo.gov/fdsys/pkg/FR-2018-09-13/pdf/2018-19864.pdf.

2/ 83 Fed Reg. at 46438.

Other proposed changes to the agency's FOIA regulations regarding exemptions from disclosure include:

- The proposed rule would prohibit the application of the deliberative process FOIA exemption to agency documents more than 25 years old.

- Regarding pre-disclosure notification for trade secrets or confidential commercial information, the proposed rule would allow 10 days from the date of notice to submitters of such information to object to disclosure; this change would bring FDA in line with departmental regulations.

- FDA also proposes to amend 21 C.F.R. § 20.86, which provides that FDA may release information that otherwise would not be available for disclosure under FOIA in certain administrative and court proceedings, to indicate that the types of proceedings listed in the regulation is not an exclusive list of proceedings in which information may be disclosed.

Other changes include proposals to:

- Establish procedures for identifying records of general interest or use to the public that are appropriate for public disclosure, and post such records in a publicly accessible electronic format.

- Indicate the exemption under which information has been redacted at the site of the redaction.

Finally, a number of the proposed amendments clarify dispute resolution procedures for FOIA requests, providing requesters with several avenues for resolving FOIA-related disputes and additional time to decide whether to pursue an appeal. For example, FDA is required under the proposed rule to provide requesters with additional avenues for resolving FOIA-related disputes beyond the appeals process by notifying them of (1) FOIA Public Liaison and Office of Government Information Services (OGIS) services; and (2) the right to seek dispute resolution services from the FOIA Public Liaison and OGIS when FDA extends the time limit to respond to requests by more than 10 additional working days (unless exceptional circumstances exist, or the agency needs to toll the response period for purposes of information or fee assessment clarity). Additionally, the proposed rule modifies the fee schedule to prohibit fees resulting from FDA's failure to comply with time limits (unless exceptional circumstances exist), establishes a process by which the agency can work with a requester to effectively limit the scope of a request, requires full and partial denial letters to include contact information for the FOIA Public Liaison and OGIS, and increases the time for transmittal of an appeal to 90 business days.

Once effective, these amendments would apply to all FOIA requests currently pending with, or received in the future by, FDA. FDA is accepting comments on the proposed rule until November 13, 2018.

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We will continue to monitor this proposed rule regarding FDA FOIA requests. Please contact us if you have any questions.