REPORTERS COMMITTEE
FOR FREEDOM OF THE PRESS

1156 15th St. NW, Suite 1250
Washington, D.C. 20005
(202) 795-9300
www.rcfp.org

Bruce D. Brown
Executive Director
bbrown@rcfp.org
(202) 795-9301

Re: Food and Drug Administration Freedom of Information Regulations, 21 CFR Parts 20 and 720

Docket No. FDA-2018-N-1622
RIN 0910-AH69

November 13, 2018

To Whom It May Concern:

The Reporters Committee for Freedom of the Press (the "Reporters Committee" or "RCFP") appreciates this opportunity to comment on the proposed updates, published on September 13, 2018 (the "Proposed Rule"), to the Food and Drug Administration's ("FDA") Freedom of Information Act, 5 U.S.C. § 552 ("FOIA" or the "Act") regulations.[1]

I. The Proposed Rule fails to properly incorporate FOIA's foreseeable harm requirement.

Section 20.20(b) of the Proposed Rule states that the FDA will "make *discretionary* disclosures of records or information exempt from disclosure under the provisions of this part whenever disclosure would not foreseeably harm an interest protected by an exemption pursuant to this part." Proposed Rule, § 20.20(b) (emphasis added). Similar language is included in section 20.82(b) of the Proposed Rule. *See id.* at § 20.82(b). This misstates the foreseeable harm requirement codified by the FOIA Improvement Act of 2016.

FOIA states that an "agency *shall* (i) withhold information under this section *only if* (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in subsection (b); or (II) disclosure is prohibited by law[.]" 5 U.S.C § 552(8)(A) (emphasis added)). The plain language of the Act thus *mandates* disclosure of information falling within one of FOIA's exemptions where the foreseeable harm requirement is not met and disclosure is not prohibited by law. To comply with FOIA, the FDA should modify sections 20.20(b) and 20.82(b) of the Proposed Rule to make clear that such disclosures are mandatory, not discretionary.[2]

---

[1] The Reporters Committee takes no position on any portion of the Proposed Rule not specifically addressed herein.

[2] For example, the Federal Energy Regulatory Commission ("FERC") added the following language to its FOIA regulations:

> The Director will only withhold information where it is reasonably foreseeable that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law or otherwise exempted from disclosure under FOIA Exemption 3.

18 CFR 388.108.

II. The Proposed Rule should clearly state that time limitations under the Act begin to run on the date of the FDA's receipt of a FOIA request.

Section 20.41 of the FDA's current FOIA regulations—which is not addressed by the Proposed Rule—calculates various time limitations under the Act starting at "the time at which a request for records is *logged in* by the Division of Freedom of Information pursuant to § 20.40(c)." 21 C.F.R. § 20.41(a) (emphasis added); *see also id.* at § 20.41(b). FOIA, however, makes clear that such calculations must begin "on the date on which the request is first *received* by the appropriate component of the agency . . . ." 5 U.S.C. § 552(a)(6)(A)(ii) (emphasis added). Therefore, the current rule is inconsistent with FOIA. The FDA should add language to the Proposed Rule clearly stating that any time limitation calculations begin at the time of receipt of a request, not the time that the request is logged.

III. The Proposed Rule should clarify its expedited processing provision.

Section 20.44(e) of the Proposed Rule states that the FDA will make a determination in response to a request for expedited processing "within 10 days of receipt by the Division of Freedom of Information of all information required to make a decision." Proposed Rule, § 20.44(e). FOIA, however, states that "a determination of whether to provide expedited processing shall be made, and notice of the determination shall be provided to the person making the request, within 10 days after the date of the request." 5 U.S.C. § 552(a)(6)(E)(ii)(I).

The Proposed Rule does not define what "all information required to make a decision" means for the purposes of a request for expedited processing. And, in any case, the Act mandates that the decision as to whether or not to grant expedited processing must be made within 10 days after the date of the request. Accordingly, to avoid any confusion, this section of the Proposed Rule should be revised to mirror the language of FOIA.

IV. The Proposed Rule must be modified to make clear that the FDA cannot ask state or local governmental entities to enter into contracts that would violate state law.

There are two provisions in section 20.88 of the Proposed Rule—which concerns "Communications with State and local government officials"—that suggest the FDA may require such officials to enter into confidentiality contracts that could violate state law. Specifically, the Proposed Rule states that the FDA may disclose "confidential commercial information" to

> State and local government officials as part of regulatory efforts, provided that: (i) The State or local government has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor of written confirmation by the Food and Drug Administration that the information no longer has confidential status . . . .

Proposed Rule, § 20.88(d)(1)(i).

The Proposed Rule also states that the FDA may disclose such information to "a State or local government scientist" if they "sign a written commitment to protect the confidentiality of the information[.]" Proposed Rule, § 20.88(d)(1)(ii)(C).

State and local government officials may not enter into contracts or other agreements that conflict with the requirements of state public records laws. *See, e.g.*, *State ex rel. Findlay Publ'g Co. v. Hancock Cty. Bd. of Commrs.*, 80 Ohio St. 3d 134, 137, 684 N.E.2d 1222, 1225 ("A public entity cannot enter into enforceable promises of confidentiality regarding public records."); *Milwaukee Journal Sentinel v. Wisconsin Dep't of Admin.*, 2009 WI 79, ¶ 53, 319 Wis. 2d 439 (rejecting argument that the "parties may, through the collective bargaining process, contract away the public's rights under [Wisconsin's public records law]."); *Lansing Ass'n of Sch. Adm'rs v. Lansing Sch. Dist. Bd. of Educ.*, 216 Mich. App. 79, 93, 549 N.W.2d 15, 23 (1996), *aff'd in part, remanded in part sub nom. Bradley v. Saranac Cmty. Sch. Bd. of Educ.*, 455 Mich. 285, 565 N.W.2d 650 (1997) (concluding that a "school district may not eliminate its statutory obligations to the public merely by contracting to do so with plaintiff . . . ."); *Paff v. W. Deptford Twp.*, No. A-3195-08T2, 2010 WL 546587, at *2 (N.J. Super. Ct. App. Div. Feb. 18, 2010) (holding that a town "could not exempt itself from the requirements of [the New Jersey Open Public Records Act], or other State law, by entering into a consent order to maintain confidentiality of discovery materials it provides to litigants in a lawsuit"). The FDA should modify sections 20.88(d)(1)(i) and § 20.88(d)(1)(ii)(C) to ensure that the Proposed Rule does not improperly indicate that the FDA may request or require state or local officials to enter into confidentiality agreements that would violate state law.

V. Conclusion

The Reporters Committee appreciates the FDA's efforts to update its FOIA regulations and urges the FDA to incorporate the comments set forth herein.

Sincerely,
The Reporters Committee for Freedom of the Press