C R I T
collaboration for research integrity and transparency

Collaboration for Research Integrity and Transparency

A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

November 6, 2018

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061, HFA-305 Rockville, MD 20852

Docket FDA-2018-N-1622

Yale Collaboration for Research Integrity and Transparency
Comments on FDA's Proposed Rule to Amend 21 CFR Parts 20 and 720 Public Information

The Yale Collaboration for Research Integrity and Transparency (CRIT) supports the proposed changes to the FDA's FOIA regulations to comply with the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) and the FOIA Improvement Act of 2016 (FOIA Improvement Act).

In particular, we applaud the proposed revisions to § 20.20(c), which require the FDA to identify records of general interest to the public for posting on its website. We urge the FDA in implementing the revised rule to take the opportunity to re-examine and implement the recommendations contained in the *Blueprint for Transparency at the U.S. Food and Drug Administration*, which provides a list of proactive changes that the FDA can make to increase transparency under existing law.

Proposed revisions to § 20.26(a)(4) require the FDA to make records available for public inspection on its electronic reading room site, that have been released to any person pursuant to a FOIA request, once 3 FOIA requests have been made for the same

157 CHURCH STREET, 17TH FLOOR
NEW HAVEN, CONNECTICUT 06510-2100
203.436.8420
EMAIL CRIT.ADMIN@YALE.EDU

records. This provision is mandated by the FOIA Improvements Act and should be implemented fully and effectively. 5 U.S.C § 552(a)(2)(D). We note that under the Food and Drug Administration Amendments Act of 2007, a similar requirement is already in effect regarding disclosure of action packages for approved drugs for which 3 FOIA requests have been made, yet does not appear to be enforced. 21 U.S.C. § 355(l)(2)(A)(ii). We recently made 3 identical FOIA requests for action packages in coordination with researchers at Dartmouth University and Johns Hopkins University, which were granted more than six months ago. The FDA has yet to post the documents on its website. We urge the FDA to promptly comply with the requirements for posting documents on its website after 3 FOIA requests are received.

We acknowledge that the FDA has proposed amendments to §20.41 regarding time limitations for the agency to promptly respond to FOIA requests, and to provide documents. However, we urge the FDA to request funding to hire sufficient additional staff so that FOIA requests, particularly those placed on the complex queue, do not languish. The *HHS Fiscal Year 2017 Freedom of Information Annual Report* indicates that the FDA had a backlog of 2,279 requests as of the end of the fiscal year, more than twice as much as any other HHS component. The report indicates that, for FOIA requests on the complex queue, the response time for perfected requests was as long as 1536 days—more than 4 years. We recently assisted researchers seeking important information relevant to the opioid epidemic who had waited more than four years to receive the documents they sought.

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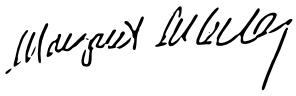
We appreciate the opportunity to comment.

Sincerely,



Margaret McCarthy
Executive Director

157 CHURCH STREET, 17TH FLOOR
NEW HAVEN, CONNECTICUT 06510-2100
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EMAIL CRIT.ADMIN@YALE.EDU