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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 
[Docket No. FDA–2019–N–1482]

Scientific Data and Information About 
Products Containing Cannabis or 
Cannabis-Derived Compounds; 
Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is 
extensiong the comment period for the notice that appeared in the Federal 
Register of April 3, 2019. The notice announced a public hearing to obtain 
scientific data and information about the safety, manufacturing, product 
quality, marketing, labeling, and sale of products containing cannabis or 
cannabis-derived compounds. In addition, it notified the public that FDA 
was establishing a docket for public comment on this hearing and that the 
docket would close on July 2, 2019. We are extending the comment period to 
give interested parties more time to comment.

DATES: FDA is extending the comment period on the notice published in the Federal 
Register of April 3, 2019 (84 FR 12969). Submit either electronic or 
written comments by July 16, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, 
untimely filed comments will not be 
considered. Electronic comments must 
be submitted on or before July 16, 2019. The https://www.regulations.gov 
electronic filing system will accept 
comments until 11:59 p.m. Eastern Time at the end of July 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are 
postmarked or the delivery service 
acceptance receipt is on or before that 
date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your 
comment will be made public, you are solely responsible for ensuring that your 
comment does not include any 
confidential information that you or a 
third party may not wish to be posted, 
such as medical information, your or 
anyone else’s Social Security number, or 
confidential business information, such as 
a manufacturing process. Please note 
that if you include your name, contact 
information, or other information that 
identifies you in the body of your 
comments, that information will be 
posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you 
do not wish to be made available to the public, submit the comment as a 
written/paper submission and in the 
manner detailed (see “Written/Paper 
Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for 
written/paper submissions): Dockets 
Management Staff (HFA–305), Food and 
Drug Administration, 5630 Fishers 
Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments 
submitted to the Dockets Management 
Staff, FDA will post your comment, as 
well as any attachments, except for 
information submitted, marked and 
identified, as confidential, if submitted 
as detailed in “Instructions.”

Instructions: All submissions received 
must include the Docket No. FDA– 
2019–N–1482 for “Scientific Data 
and Information About Products Containing 
Cannabis or Cannabis-Derived 
Compounds.” Received comments, 
those filed in a timely manner (see 
ADDRESSES), will be placed in the docket and, except for those submitted as 
“Confidential Submissions,” publicly 
viewable at https://www.regulations.gov 
or at the Dockets Management Staff 
between 9 a.m. and 4 p.m., Monday 
through Friday.

• Confidential Submissions—To 
submit a comment with confidential 
information that you do not wish to be 
made publicly available, submit your 
comments only as a written/paper 
submission. You should submit two copies total. One copy will include 
the information you claim to be confidential 
with a heading or cover note that states 
“THIS DOCUMENT CONTAINS 
CONFIDENTIAL INFORMATION.” We 
will review this copy, including the 
claimed confidential information, in our 
consideration of comments. The second 
copy, which will have the claimed 
confidential information redacted/ 
blacked out, will be available for public 
viewing and posted on https:// www.regulations.gov. Submit both 
copies to the Dockets Management Staff. 
If you do not wish your name and 
contact information to be made publically 
available, you can provide this 
information on the cover sheet and not 
in the body of your comments and you 
must identify this information as 
“confidential.” Any information marked 
as “confidential” will not be disclosed 
except in accordance with 21 CFR 10.20 
and other applicable disclosure law. For 
more information about FDA’s posting 
of comments to public docket, see 80 
FR 56469, September 18, 2015, or access 
the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-
23389.pdf.

Docket: For access to the docket to 
read background documents or the
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records

AGENCY: Department of Health and Human Services.

ACTION: Notice of a new system of records, and rescission of related systems.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is establishing a new department-wide system of records, titled HHS Correspondence, Customer Service, and Contact List Records, system no. 09–90–1901. The new system of records replaces 13 existing systems of records which are rescinded in this notice, and it includes additional records not currently covered by any SORN. Two other related systems of records are also rescinded in this notice, but not replaced by the new SORN, because those records no longer exist.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable June 20, 2019, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by July 22, 2019.

ADDRESSES: The public should submit written comments on this notice, by mail or email, to Beth Kramer, HHS Privacy Act Officer, 200 Independence Ave. SW, Suite 729H, Washington, DC 20201, or beth.kramer@hhs.gov. Comments will be available for public viewing at the same location. To review comments in person, please contact Beth Kramer at beth.kramer@hhs.gov or 202–690–6941.

FOR FURTHER INFORMATION CONTACT: General questions may be submitted to Beth Kramer, HHS Privacy Act Officer, at 200 Independence Ave. SW, Suite 729H, Washington, DC 20201, or beth.kramer@hhs.gov. or 202–690–6941.

SUPPLEMENTARY INFORMATION:

I. Background on New SORN 09–90–1901

HHS is establishing this new department-wide system of records to cover records about individuals within or outside HHS which are retrieved by personal identifier and used in managing HHS correspondence and customer service functions, including help desk and call center activities, dissemination of publications, studies, opinions, unrestricted datasets, and other information, and mailing and contact lists, unless covered by a more specific system of records notice (SORN). It will include the records currently covered in 13 related SORNs, in order to replace and rescind those SORNs, but with revisions where needed, to provide updated descriptions of those records. It will also include other functionally similar records not currently covered by any SORN. The up-to-date records descriptions used in the new SORN differ from the descriptions used in the replaced SORNs in these respects:

- The System Manager contact information has been updated and is grouped by record type.
- The System Location section refers to the contact information shown in the System Manager section.
- The Authorities section now cites 5 U.S.C. 301, 305; 21 U.S.C. 301 et seq.; 31 U.S.C. 1115(b)(6); 40 U.S.C. 11313; 42 U.S.C. 201 et seq.; 44 U.S.C. 3101; E.O. 11583; and E.O. 13571. This differs from the authorities cited in each replaced SORN as follows:

  e. SAMHSA SORN 09–30–0033 cited portions of title 42 of the United States Code, which is cited in the new SORN, and these authorities not cited in the new SORN: 8 U.S.C. 1522 note, as amended by sec. 501(c) of Public Law 96–422; E.O. 12341; and sec. 413 of Public Law 93–288 as amended and redesignated as sec. 416 by Public Law 100–107 [sic; probably should be Public Law 101–707, amending 42 U.S.C. 5183].
  f. These SORNs cited none of the authorities cited in the new SORN:

ii. OS SORN 09–90–0161 cited 42 U.S.C. 300u–6;
iii. CDC SORN 09–20–0050 cited 29 U.S.C. 670;
iii. CMS SORN 09–70–3005 cited 42 U.S.C. 1306(a) and 42 CFR 401.101–401.148; and

- The new SORN provides broader and more detailed descriptions of the categories of records and the purposes for which the records are used than were in each replaced SORN, in recognition that some of the records interrelate with each other and may be maintained and used together, and by more than one office, to achieve certain purposes. Each replaced SORN