

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PCNASP Awardee .....	Hospital inventory .....	9	1	8
	In-hospital care data .....	9	4	30/60
	Pre-hospital care data .....	2	4	30/60
	7	4	2	
	Post-hospital transition of care data .....	7	4	30/60
PCNASP Hospital Partners .....	2	4	1	
	Hospital Inventory .....	378	1	30/60

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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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 extending 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 publicly 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 dockets, 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

electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** April Alexandrow, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Room 3147, Silver Spring, MD 20993, 301-796-5363.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 3, 2019, FDA published a notice announcing 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, we notified the public that FDA was establishing a docket for public comment on this hearing. The information from the hearing and comments provided to the docket will inform our regulatory oversight of these products and is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products. We asked that comments be submitted by July 2, 2019.

At the public hearing, we received requests for a 30-day extension of the comment period for the notice. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to the questions that appeared in the notice requesting data and other evidence in support of answers.

We have considered the requests and are extending the comment period for another 14 days, until July 16, 2019. We believe that a 14-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential further action on these important issues.

Dated: June 14, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-13122 Filed 6-19-19; 8:45 am]

**BILLING CODE 4164-01-P**

## 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 rescindment 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](mailto: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](mailto: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](mailto: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:
  - a. OS SORNs 09-37-0001, 09-90-0027, 09-90-0037, 09-90-0038, and 09-90-0072 and HRSA SORN 09-15-0059 cited only one of the authorities cited in the new SORN, 5 U.S.C. 301.
  - b. NIH SORN 09-25-0106 cited two authorities cited in the new SORN, 5 U.S.C. 301 and 44 U.S.C. 3101.
  - c. OS SORN 09-90-0001 cited 5 U.S.C. 301 and one authority not cited in the new SORN: 40 U.S.C. 486(c).
  - d. FDA SORN 09-10-0004 cited 42 U.S.C. 201 *et seq.*, which is cited in the new SORN, and two authorities not cited in the new SORN: 21 U.S.C. 321 *et seq.* and 21 CFR part 5.
  - 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:
    - i. OS SORN 09-90-0161 cited 42 U.S.C. 300u-6;
    - ii. CDC SORN 09-20-0059 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
    - iv. SAMHSA SORN 09-30-0051 cited sec. 501 of the Public Health Service Act (42 U.S.C. 290a) as amended by Public Law 102-321 and Public Law 106-310.
  - 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