instead established a tolerance of 30 ppb for QCA, and granted the supplemental approval for carbadox. Subsequent to the 1998 supplemental approval, CVM has evaluated additional information that undermines its previous conclusions that carcinogenic residues deplete within 72 hours and that QCA is the only residue detectable at 72 hours postdosing. These new data reinforce the inadequacy of the currently approved method and clarify the need for a method that satisfies the requirements of part 500. See, supra, Section II.C.

B. The Current Approved Method for Carbadox That Measures QCA as the Marker Residue for Carbadox Is Inadequate

Under section 512(d)(1)(I) of the FD&C Act, carcinogenic new animal drugs, such as carbadox, must have a method of detection, prescribed or approved by regulation, to ensure that no residue of carcinogenic concern persists in any edible tissue or other food derived from a treated animal. CVM has implemented this statutory requirement through its SOM regulations in part 500, subpart E, which require that each carcinogenic new animal drug have a marker residue with a known relationship to the residue of carcinogenic concern. This relationship is necessary to establish a concentration of the marker residue (the R_m) that ensures any residue of carcinogenic concern in a specific edible tissue is below the level corresponding to maximum lifetime risk of cancer in the test animal of 1 in 1 million (the S_m), based on calculations that consider the entire diet (the S_o). The approved method must have a limit of detection less than or equal to the R_m.

Although CVM approved the current method for carbadox as part of the supplemental NADA in January 1998 and designated the S_m and S_o, we did not require the sponsor to provide data showing the relationship between QCA and the residue of carcinogenic concern and therefore did not designate an R_m. Nor did we require the sponsor to identify a regulatory method with a limit of detection less than or equal to the R_m. Without an R_m and an appropriate regulatory method for detecting when the marker residue falls below the R_m, it is impossible to determine that the residue of carcinogenic concern falls below the S_m and S_o at the established withdrawal period. Accordingly, it is impossible, based on information currently available, to use the current approved method to ensure compliance with the operational definition of no residue.

Furthermore, based on studies conducted since 1998, CVM has reevaluated the conclusions that originally led us to determine that assignment of a tolerance of 30 ppb for QCA in swine liver would assure that the residue of carcinogenic concern would remain below their respective S_o in all edible tissues. CVM concludes, based on its review of the data, that carcinogenic residues persist longer than previously known. Because there is no regulatory method that detects when the residue of carcinogenic concern falls below the limit of detection for the R_m, the current approved method is inadequate for monitoring compliance with FDA's operational definition of no residue. See § 500.84(c)(3). Accordingly, the approved method for carbadox does not satisfy the statutory or regulatory requirements.

IV. Conclusion

In the January 1998 approval of the supplemental NADA for carbadox, CVM previously determined that carbadox and its metabolites, including DCBX, induce cancer in animals but that no such residues of the drug would be found in edible tissues after the preslaughter withdrawal period by the approved regulatory methods of examination. However, the failure to establish an R_m or a relationship between QCA residues and residue of carcinogenic concern in animal tissue during the 1998 process leads CVM to now conclude that the current approved method does not meet the requirements of the FD&C Act and the SOM regulations and is inadequate to monitor carbadox residues in compliance with FDA's operational definition of no residue. New information available to CVM since the approval of the January 1998 supplemental NADA reinforces the importance of having an approved regulatory method that complies with the SOM regulations. Therefore, we are proposing to revoke the current approved method.

V. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Suárez, A.F. and Arnold, D., Addendum to the carbadox monograph prepared by the 36th meeting of the Committee and published in the FAO Food and Nutrition Paper 41/3, Rome 1991. Available at: *http://www.fao.org/fileadmin/user_upload/vetdrug/docs/41-15-carbadox.pdf* (accessed on April 7, 2020).
2. Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Carbadox. Available at: *https://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=2176* (accessed on April 7, 2020).
3. Internet Archive of Health Canada, Drug and Health Products (June 2008), *https://web.archive.org/web/20080609050022/http://www.hc-sc.gc.ca/dhp-mps/vet/faq/faq_mrl-lmr-eng.php* (accessed on April 7, 2020).
4. Australian Pesticides and Veterinary Medicines Authority, ''Substances not permitted for use on food-producing animals in Australia,'' *https://apvma.gov.au/node/11626* (accessed on April 7, 2020).

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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the current regulations, step (4) requires the development of a method that complies with the operational definition of no residue (the method's LOD is less than or equal to the R_m).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0278]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 19, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting

comments or requesting information, please include the document identifier 0990–0278 and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Federal wide Assurance Form.

Type of Collection: Extension.

OMB No. 0990–0278—Office of the Assistant Secretary for Health, Office for Human Research Protections—Federal Wide Assurance Form

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting a three year extension of the Federal wide Assurance (FWA) form. The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Respondents are institutions engaged in human subject's research that is conducted or supported by HHS.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Federal wide Assurance (FWA)	14,000	2.0	0.50	14,000
Total				14,000

Terry Clark,

Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–15585 Filed 7–17–20; 8:45 am]

BILLING CODE 4150–28–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 a System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is establishing a new department-wide system of records, 09–90–2001, Records Used for Surveillance and Study of Epidemics, Preventable Diseases and Problems. The new system of records replaces, and is broader than, a similar system of records maintained by HHS' Centers for Disease Control and Prevention (CDC), which HHS is rescinding in this notice, 09–20–0113 Epidemic Investigation Case Records.

DATES: The new department-wide system of records is applicable July 20, 2020, subject to a 30-day period in which to comment on the routine uses. The rescindment of the CDC system of records is applicable August 19, 2020. Submit any comments by August 19, 2020.

ADDRESSES: The public should address written comments by email to *beth.kramer@hhs.gov* or by mail to Beth Kramer, HHS Privacy Act Officer, FOIA/Privacy Act Division, Office of the Assistant Secretary for Public Affairs, 200 Independence Ave. SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: General questions about the new system of records and the related rescindments may be submitted by email to *beth.kramer@hhs.gov* or by mail to Beth Kramer, HHS Privacy Act Officer, FOIA/Privacy Act Division, Office of the Assistant Secretary for Public Affairs, 200 Independence Ave. SW, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: In the winter and spring of 2020, spread of the novel coronavirus, SARS–CoV–2, which causes the disease known as COVID–19, required HHS to expand its recordkeeping in order to respond to the pandemic. Prior to 2020, CDC maintained records about epidemiological studies and surveillance of disease problems. However, HHS' experience during the COVID–19 pandemic made clear that other components, not just CDC, must collect epidemiologic and public health surveillance records about individuals to support the Department's response. For example, the Office of the Assistant Secretary for Health (OASH) is managing records about tests for COVID–19 or its antibodies, some of which are subject to the Privacy Act.

Therefore, the Department has decided to expand the existing system of records of the CDC, 09–20–0113 Epidemic Investigation Case Records, and re-establish it under a new system number and name as a department-wide system of records covering all parts of the Department that may maintain epidemiological and surveillance records necessary to support the Department's response to the pandemic.

The new department-wide system of records includes the records covered in CDC system of records 09–20–0113, which HHS rescinds in this notice, but is broader in that it covers records used for surveillance and investigation of epidemics, preventable diseases and health problems maintained by *any* component of HHS, not just CDC. This department-wide system of records notice (SORN) differs from the CDC SORN it is replacing in these additional respects:

- It is formatted to comply with OMB Circular A–108.
- The System Manager section includes updated contacts for CDC records, and adds contacts for OASH records and ''records maintained by other HHS components.''
- The Authorities section includes one additional authority not included in the CDC SORN: 42 U.S.C. 247d–6d.
- The Purpose description is department-wide.
- The Categories of Individuals section uses different wording from, but identifies the same categories of individuals as, the CDC SORN.
- The Categories of Records section identifies the categories as ''medical records and related documents,'' including ''case reports, lab requisition