The burden estimate has not changed, and remains the same.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–00237 Filed 1–9–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA 2017–N–4951]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

EXTRALABEL DRUG USE IN ANIMALS—21 CFR PART 530

OMB Control Number 0910–0325—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103–396) allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level (21 CFR 530.22(b)). Although, to date, we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

In the Federal Register of June 26, 2017 (82 FR 28858), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.22(b), Submission(s) of Analytical Method</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4,160</td>
<td>8,320</td>
</tr>
</tbody>
</table>

*There are no capital costs or operating and maintenance costs associated with this collection of information.

DATES: Fax written comments on the collection of information by February 9, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Leslie Kux, Associate Commissioner for Policy, 395–7285, or emailed to oira_submission@omb.eop.gov. Also include the OMB control number 0910–0332. All comments should be identified with the OMB control number 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7226, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.
account the probable risks and benefits of currently available devices or alternative forms of treatment. Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2). The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

In the Federal Register of October 16, 2017 (82 FR 48096), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

### Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for HUD designation—814.102</td>
<td>19</td>
<td>1</td>
<td>19</td>
<td>40</td>
<td>760</td>
</tr>
<tr>
<td>HDE Application—814.104</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>320</td>
<td>960</td>
</tr>
<tr>
<td>HDE Amendments and resubmitted HDEs—814.106</td>
<td>6</td>
<td>5</td>
<td>30</td>
<td>50</td>
<td>1,500</td>
</tr>
<tr>
<td>HDE Supplements—814.108</td>
<td>110</td>
<td>1</td>
<td>110</td>
<td>80</td>
<td>8,800</td>
</tr>
<tr>
<td>Notification of withdrawal of an HDE—814.116(e)(3)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Notification of withdrawal of Institutional Review Board approval—814.124(b)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Periodic reports—814.126(b)(1)</td>
<td>35</td>
<td>1</td>
<td>35</td>
<td>120</td>
<td>4,200</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16,223</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

### Table 2—Estimated Annual Recordkeeping Burden

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeping</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDE Records—814.126(b)(2)</td>
<td>247</td>
<td>1</td>
<td>247</td>
<td>2</td>
<td>494</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

### Table 3—Estimated Annual Third-Party Disclosure Burden

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification of emergency use—814.124(a)</td>
<td>22</td>
<td>1</td>
<td>22</td>
<td>1</td>
<td>22</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, i.e., fiscal years 2014 through 2016. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 35 respondents with approved HUD applications. Under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 247.

The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall decrease of 2,971 hours to the total estimated annual reporting burden.

There have been no program changes and the estimated Average Burden per Response has not changed for any of the information collections since the last OMB approval.


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–00241 Filed 1–9–18; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915–0311—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.