To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–3427 End Stage Renal Disease Application and Survey and Certification Report

CMS–484, 846, 854, 847, 848, 849, 10125, and 10126 Durable Medical Equipment Medicare Administrative

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage. *Form Number:* CMS–3427 (OMB control number: 0938–0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 7,493; *Total Annual Responses:* 2,473; *Total Annual Hours:* 824. (For policy questions regarding this collection contact Jennifer Milby at 410–786–8828).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; *Use:* The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (*e.g.,* patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (*e.g.,* physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN electronically to CMS, along with a claim for reimbursement. *Form Numbers:* CMS–484, 846, 847, 848, 849, 10125, 10126 (OMB control number: 0938–0679); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,335,658; *Total Annual Responses:* 1,335,658; *Total Annual Hours:* 267,132. (For policy questions regarding this collection contact Melissa Singer at 410–786–0365.)

Dated: October 23, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–23504 Filed 10–25–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10400]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *November 27, 2019.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/*

PaperworkReductionActof1995/PRA-Listing.html

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Establishment of Exchanges and Qualified Health Plans; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L.111–152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that are certified as meeting certain standards.

As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange assumed responsibilities related to the certification and offering of QHPs. Under 45 CFR 156.280(e)(5)(ii), each QHP issuer that offers non-excepted abortion services must submit to the State Insurance Commissioner a segregation plan describing how the QHP issuer establishes and maintains separate payment accounts for any QHP covering non-excepted abortion services, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with PPACA section 1303 and applicable regulations. This segregation plan is used to verify that the QHP issuer's financial and other systems fully conform to the segregation requirements required by the PPACA. *Form Number:* CMS–10400 (OMB control number 0938–1156); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 210; *Number of Responses:* 210; *Total Annual Hours:* 580. For questions regarding this collection contact Michele Oshman at 410–786–4396.

Dated: October 23, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–23506 Filed 10–25–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3708]

InvaGen Pharmaceuticals, Inc.; Proposal To Withdraw Approval of an Abbreviated New Drug Application for Trandolapril Tablets; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of an abbreviated new drug application (ANDA) for trandolapril tablets and is announcing an opportunity for the holder of the ANDA to request a hearing on this proposal. The basis for the proposal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA.

DATES: InvaGen Pharmaceuticals, Inc. may submit a request for a hearing by November 27, 2019. Submit all data, information, and analyses upon which the request for a hearing relies by December 27, 2019. Submit electronic or written comments by December 27, 2019.

ADDRESSES: The request for a hearing may be submitted by InvaGen Pharmaceuticals, Inc. by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2019–N–3708 for ''InvaGen Pharmaceuticals, Inc.; Proposal to Withdraw Approval of an Abbreviated New Drug Application for Trandolapril Tablets; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

InvaGen Pharmaceuticals, Inc. may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data and analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which