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–2017–F–4399 for ''Zinpro Corp.; Filing of Food Additive Petition (Animal Use).'' 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.'' The Agency will review this copy, including the claimed confidential information, in its 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: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration (HFV–224), 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 22, 2017 (82 FR 44367), FDA announced that Zinpro Corp., 10400 Viking Dr., Suite 240, Eden Prairie, MN 55344 had filed a petition (FAP 2300) proposing to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of chromium DL-methionine as a nutritional source of chromium in cattle feed. Zinpro has amended the petition by changing the feeding rate.

Zinpro has submitted a revised environmental assessment which the Agency is placing on public display at the Dockets Management Staff for public review and comment (see **DATES** and **ADDRESSES**).

Dated: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25903 Filed 11–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2019–F–5401]

Alzchem Trostberg GmbH; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; petition for rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that Alzchem Trostberg GmbH has filed a petition proposing that the food additive regulations be amended to provide for the safe use of guanidinoacetic acid as a precursor of creatine in poultry feeds.

DATES: The food additive petition was filed on September 25, 2019.

ADDRESSES: For access to the docket, 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: Carissa Adams, Center for Veterinary Medicine, Food and Drug Administration,7519 Standish Pl., Rockville, MD 20855, 240–402–6283, *Carissa.Adams@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2309) has been filed by Alzchem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr.-Albert-Frank-Str. 32, 83308 Trostberg, Germany. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of guanidinoacetic acid as a precursor of creatine in poultry feeds.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is

required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25904 Filed 11–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2019–HA–0056]

RIN 0720–AB73

TRICARE; Reimbursement of Ambulatory Surgery Centers and Outpatient Services Provided in Cancer and Children's Hospitals

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The Department of Defense, Defense Health Agency, is proposing to amend its reimbursement of ambulatory surgery centers (ASC) and outpatient services provided in Cancer and Children's Hospitals (CCHs). Proposed revisions are in accordance with the TRICARE Statute that requires TRICARE's payment methods for institutional care be determined, to the extent practicable, in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare. In accordance with this requirement, TRICARE proposes to adopt Medicare's payment methodology for ASC, and adopt Medicare's payment methodology for outpatient services provided in CCHs.

DATES: Written comments received at the address indicated below by January 28, 2020 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal Rulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Elan Green, Defense Health Agency, 303–676–3907.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this rule is to propose TRICARE regulation modifications necessary to implement for Ambulatory Surgery Centers (ASC) and Cancer and Children's Hospitals (CCHs) the statutory requirement that payments for TRICARE institutional services ''shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare].'' Although Medicare's reimbursement methods for ASC and CCHs are different, it is prudent to propose adopting both the Medicare ASC system and to adopt the Outpatient Prospective Payment System (OPPS) with hold-harmless adjustments (meaning the provider is not reimbursed less than their costs) for CCHs simultaneously to align with our statutory requirement to reimburse like Medicare at the same time. This rule sets forth the proposed regulatory modifications necessary to implement TRICARE reimbursement methodologies similar to those applicable to Medicare beneficiaries for outpatient services rendered in ASCs and cancer and children's hospitals.

1. TRICARE proposes adopting the Medicare reimbursement methodology for ASCs. Currently, TRICARE reimburses surgical services performed in TRICARE authorized ambulatory surgery settings (*i.e.,* freestanding ASCs and other TRICARE providers exempt from the TRICARE OPPS reimbursement methodology including cancer and children's hospitals) institutional facility costs on the basis of prospectively determined amounts, in accordance with Title 32 Code of Federal Regulations (CFR) 199.14(d). The current system was modeled after Medicare's previous ASC reimbursement system. TRICARE's current reimbursement system for services provided in these ambulatory surgery settings is based on Medicare's retired system, and is difficult to update. Adoption of Medicare's ASC reimbursement system will bring TRICARE reimbursement for ambulatory surgery care into alignment with the statutory requirement that payment methods for institutional care be, to the extent practicable, in accordance with the same reimbursement rules used by Medicare.

2. TRICARE proposes to adopt the Medicare payment methodology for outpatient services provided in CCHs. In a final rule, published December 10, 2008 (73 FR 74945–74966), TRICARE adopted Medicare's payment methodology for outpatient hospital services—the Outpatient Prospective Payment System (OPPS). Under Medicare, CCHs were held harmless and were paid the full amount of the decrease they experienced (as prior to OPPS the hospital had been paid 100% of their costs) after the implementation of OPPS, under section 1833(t)(7) of the Social Security Act. These payments are transitional outpatient payments (TOPs). Because of the complexity and because of the administrative burden/expense of calculating and maintaining the TOPs, TRICARE opted to totally exempt CCHs from OPPS initially. The agency is now revisiting the exemption of CCHs from OPPS. In this proposed rule, we propose that TRICARE adopt the Medicare methodology for reimbursement of outpatient facility services (including ambulatory surgery) rendered in a cancer or children's hospital, with modifications to address the administrative burden and complexity. The Defense Health Agency (DHA) now has the capability, and it is feasible, to adopt these reimbursement provisions with a modification that the hold-harmless provisions will be calculated annually, rather than in monthly interim payments.

B. Summary of the Major Provisions of the Proposed Rule

1. *Adopting Medicare's Ambulatory Surgical Center Reimbursement System for TRICARE Authorized Ambulatory Surgery Centers.* Per Title 10 United States Code (U.S.C.), 1079(i)(2), TRICARE's payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules used by Medicare. Under this proposed rule, TRICARE will reimburse ASCs for ambulatory surgical services using a method similar to Medicare's ASC reimbursement methodology. Under the proposed TRICARE ASC reimbursement method, payment for a TRICARE patient will be made at the lower of the billed charge or the Medicare-determined ASC payment rate with applicable TRICARE