applicant compliance with CMS requirements and to gather data used to support determination of contract awards. *Form Number:* CMS–10237 (OCN 0938–0935). *Frequency:* Yearly. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 566. *Total Annual Responses:* 566. *Total Annual Hours:* 22,955. (For policy questions regarding this collection contact Barbara Gullick at 410–786–0563. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Notice of Denial of Medical Coverage (or Payment); *Use:* Section 1852(g)(1)(B) of the Social Security Act (SSA) requires Medicare health plans to provide enrollees with a written notice in understandable language that explains the plan's reasons for denying a request for a service or payment for a service the enrollee has already received. The written notice must also include a description of the applicable appeals processes. Regulatory authority for this notice is set forth in Subpart M of Part 422 at 42 CFR 422.568, 422.572, 417.600(b), and 417.840.

Section 1932 of the Social Security Act (SSA) sets forth requirements for Medicaid managed care plans, including beneficiary protections related to appealing a denial of coverage or payment. The Medicaid managed care appeals regulations are set forth in Subpart F of Part 438 of Title 42 of the CFR. Rules on the content of the written denial notice can be found at 42 CFR § 438.404.

This notice combines the existing Notice of Denial of Medicare Coverage with the Notice of Denial of Payment and includes *optional* language to be used in cases where a Medicare health plan enrollee also receives full Medicaid benefits that are being managed by the Medicare health plan. *Form Number:* CMS–10003 (OCN: 0938–0829). *Frequency:* Occasionally. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 665. *Total Annual Responses:* 6,960,410. *Total Annual Hours:* 1,159,604. (For policy questions regarding this collection contact Gladys Wheeler at 410–786–0273. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 4, 2012:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 29, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–16514 Filed 7–5–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187 Formerly Docket No. 2000D–1267]

Draft Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management To Reduce the Risk of Transfusion-Transmitted Malaria; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated June 2012. The draft guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, allowing their reentry, and product management to reduce the risk of transfusion-transmitted malaria. This guidance replaces the draft guidance entitled ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria'' dated June 2000. The draft guidance, when finalized, will supersede the FDA memorandum to all registered blood establishments entitled ''Recommendations for Deferral of Donors for Malaria Risk'' dated July 26, 1994. The recommendations contained in the draft guidance are not applicable to donors of Source Plasma.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated June 2012. The draft guidance document provides blood establishments that collect blood and

blood components with recommendations for questioning and deferring donors of blood and blood components, and allowing their reentry, to reduce the risk of transfusion-transmitted malaria. This draft guidance document also provides recommendations for product management, including recommendations regarding product retrieval and quarantine, and notification of consignees of blood and blood components in the event that a blood establishment determines that blood or blood components have been collected from a donor who should have been deferred due to possible malaria risk. Finally, the draft guidance revises FDA's policy regarding donors who are residents of non-endemic countries and who have traveled to the Mexican states of Quintana Roo or Jalisco, and allows for donation without any deferral for malaria risk, provided the donor meets all other donor eligibility criteria.

The draft guidance replaces the draft guidance entitled ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria'' dated June, 2000, and, when finalized, will supersede the FDA memorandum to all registered blood establishments entitled ''Recommendations for Deferral of Donors for Malaria Risk,'' dated July 26, 1994. Since publication of these documents, FDA convened a scientific workshop on ''Testing for Malarial Infections in Blood Donors'' in July 2006, and also discussed the issue of blood donor deferral for malaria risk with the FDA Blood Products Advisory Committee (BPAC) on several occasions. The recommendations contained in the draft guidance are based, in part, on recommendations from BPAC, the public comments received on the earlier documents, and the comments received during the scientific workshop. In addition, FDA is aware that dengue viruses are endemic in Quintana Roo and Jalisco. FDA is currently evaluating the risk of dengue virus infections in U.S. blood donors that are acquired either locally or elsewhere in the world, including in Mexico, and may address this issue in future guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 640 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 630.6 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16528 Filed 7–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0563]

Single-Ingredient, Immediate-Release Drug Products Containing Oxycodone for Oral Administration and Labeled for Human Use; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to take enforcement action against all unapproved single-ingredient, immediate-release drug products that contain oxycodone hydrochloride (hereinafter ''oxycodone'') for oral administration and are labeled for human use, and persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. Unapproved oxycodone drug products have been implicated in reports of medication errors causing serious adverse events. In addition, some of these products omit important warning information in their labeling. Single-ingredient, immediate-release oxycodone drug products are new drugs that require approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs) to be legally marketed.

DATES: This notice is effective July 6, 2012. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section IV.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA–2012–N–0563 and directed to the appropriate office listed in this document.

Applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)): Division of Anesthesia, Analgesia, and Addiction Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Applications under section 505(j) of the FD&C Act: Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

All other communications: Astrid Lopez-Goldberg, Office of Unapproved Drugs and Labeling Compliance, Division of Prescription Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5368, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Astrid Lopez-Goldberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5368, Silver Spring, MD 20993–0002, 301–796–3485, *astrid.lopezgoldberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Oxycodone is an opioid drug that is primarily used as an analgesic to relieve