for these studies and to provide an adequate degree of consumer protection, the Agency issued GLP regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with good laboratory practices. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses, and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

Recordkeeping is necessary to document the conduct of nonclinical laboratory studies of FDA-regulated products to ensure the quality and integrity of the resulting final study report on which a regulatory decision may be based. Written SOPs and records of actions taken are essential for testing facilities to implement GLP's effectively. Further, they are essential for FDA to be able to determine a testing facility's compliance with the GLP regulations in part 58.

Description of Respondents: The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
58.29(b); Personnel	300	20	6,000	0.21 (13 minutes)	1,260
58.35(b)(1)–(b)(6) and (c); Quality assurance	300	270.76	81,228	3.36	279,926
58.35(b)(7); Quality assurance	300	60.25	18,075	1	18,075
58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	0.09 (5 minutes)	1,620
58.81(a)–(c); SOPs	300	301.8	90,540	0.14 (8 minutes)	12,676
58.90(c) and (g); Animal care	300	62.7	18,810	0.13(8 minutes)	2,445
58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8	17,700
58.107(d); Test and control article handling	300	1	300	4.25	1,275
58.113(a); Mixtures of articles with carriers	300	15.33	4,599	6.8	31,273
58.120; Protocol	300	15.38	4,614	32.7	150,878
58.185; Nonclinical laboratory study results	300	60.25	18,075	27.65	499,774
58.195; Retention of records	300	251.5	75,450	3.9	294,255
Total					1,311,157

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

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13787 Filed 6–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0984]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration

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.

DATES: Fax or email written comments on the collection of information by July 14, 2014.

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 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (OMB Control Number 0910–0045)

In the **Federal Register** of September 6, 2013 (78 FR 54899), FDA announced the availability of a draft guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System

for Drug Establishment Registration.'' Sections 701 and 702 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This draft guidance specifies the UFI system as follows. At this time, FDA's preferred UFI for a drug establishment is the Data Universal Numbering System D–U–N–S (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting the Web site for Dun and Bradstreet. As explained in the guidance, however, if a company wants to use an alternative UFI for its drug establishment, it may contact FDA via email at *edrls@fda.hhs.gov.*

OMB has previously approved existing information collections associated with the electronic submission of initial and annual registration of domestic and foreign drug establishments, as described in part 207 (21 CFR part 207) and the guidance document ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing'' (the 2009 Guidance) (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072339.pdf*), under OMB control number 0910–0045. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) required that drug establishment registration and drug listing information must be submitted electronically unless a waiver is granted. As part of its recommendations to facilitate electronic submission of drug establishment registration information, as required by statute, the 2009 guidance explained that FDA is adopting the use of extensible markup language files in a standard structured product labeling format for the electronic submission of drug establishment registration and drug listing information. The 2009 guidance also explained that the automated submission process functions most efficiently and effectively when the information is provided in a standardized format with defined code sets and codes. In addition, the 2009 guidance requested, among other things, the electronic submission of a site-specific DUNS number for each entity as part of the registration information submitted electronically. In FDA's experience, all firms currently registered with FDA under section 510 of the FD&C Act and part 207 have submitted their DUNS number as requested in the 2009 guidance.

The guidance modifies the currently approved information collections associated with drug establishment registration, consistent with subsequent statutory enactment. In July 2012, Congress enacted FDASIA, sections 701 and 702 of which direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI. Because drug firms generally possess, and for those already registered, have previously provided, a DUNS number for each facility, FDA expects that consistent with the proposed UFI system, they will submit DUNS numbers as the UFIs for drug establishments. Although the change in statutory authority described in this document will alter the legal basis for submission of the DUNS number, it is not expected to have any other impact on the previously approved collection of information. FDA expects that the DUNS number will continue to be submitted by the same respondents, with the same frequency, as part of the same electronic registration submission previously approved under the PRA, and the Agency will continue to use the information for the same purposes, in furtherance of its mission to protect the public health.

While FDA anticipates that firms will submit DUNS as UFI, the guidance also suggests that firms who want to submit an alternative identifier contact FDA. FDA estimates that no more than one respondent per year will invoke this option. FDA estimates that it would require on average 1 hour for a company to contact FDA and identify its proposed alternative UFI.

In the **Federal Register** of September 6, 2013 (78 FR 54899), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments that did not pertain to the information collection. Upon review of these comments FDA does not plan to revise the information collection.

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13788 Filed 6–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–P–0136 (Formerly Docket No. 2006P–0496) and Docket No. FDA–2007–P–0353 (Formerly Docket No. 2007P–0034)]

Determination That AZO GANTANOL (Phenazopyridine Hydrochloride, Sulfamethoxazole) Tablet, 100 Milligrams/500 Milligrams, and AZO GANTRISIN (Phenazopyridine Hydrochloride, Sulfisoxazole) Tablet, 50 Milligrams/500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that AZO GANTANOL (phenazopyridine hydrochloride (HCl) and sulfamethoxazole) Tablet, 100 milligrams (mg)/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for phenazopyridine HCl and sulfamethoxazole tablet, 100 mg/500 mg, and phenazopyridine HCl and sulfisoxazole tablet, 50 mg/500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of