Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirements in part 1270. Based on information provided by CBER’s database system, 90% of the conventional tissue banks are members of AATB (145 x 90% = 130), and 77% of eye tissue banks are members of EBAA (112 x 77% = 86). Therefore, recordkeeping by these 216 establishments (130 + 86 = 216) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 41 establishments, which is 16% of all establishments (257 - 216 = 41, or 41/257 = 16%).

Based on CBER’s database system and information provided by industry, FDA estimates an average of two new tissue banks annually, which may be non-members of a trade association. Each new tissue bank requires an estimated 64 hours to prepare standard operating procedures (SOPs) under § 1270.31(a) through (d). The requirement for the development of these written procedures is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (b), include documenting the results and interpretation of all required infectious disease tests and results and the identity and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

In the Federal Register of March 1, 2010 (75 FR 9226), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

FDA estimates the burden of this information collection as follows:

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Recordkeepers</th>
<th>Annual Frequency per Recordkeeping</th>
<th>Total Annual Records</th>
<th>Hours per Record</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1270.31(a), (b), (c), and (d)</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>64</td>
<td>128</td>
</tr>
<tr>
<td>1270.31(a), (b), (c), and (d)²</td>
<td>41</td>
<td>1</td>
<td>41</td>
<td>24</td>
<td>984</td>
</tr>
<tr>
<td>1270.31(a) and (b)³</td>
<td>41</td>
<td>2</td>
<td>82</td>
<td>1</td>
<td>82</td>
</tr>
<tr>
<td>1270.33(a), (f), (h), and 1270.35(a) and (b)</td>
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<td>8,404</td>
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<tr>
<td>1270.35(c)</td>
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<td>15,938</td>
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<td>1270.35(d)</td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,080,888</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.
²Review and update of SOPs.
³Documentation of deviations from SOPs.


Leslie Kux,
Acting Assistant Commissioner for Policy.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the Federal Register during the first week of each month. If any laboratory’s certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at http://www.workplace.samhsa.gov and http://www.drugfreeworkplace.gov.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 101–473.
100–71. Subpart C of the Mandatory Guidelines, “Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

- ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory)
- ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264
- Aegis Analytical Laboratories, 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.)
- Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)
- Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)
- Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917
- Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310
- DynaLIFE Dx,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702/800–661–9876, (Formerly: Dynacare Kasper Medical Laboratories)
- ElSholy Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609,
- Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630
- Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387
- Laboratory Corporation of America Holdings, 69 First Ave., Ranitan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)
- Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 686–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)
- LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
- Maxxam Analytics,* 6740 Campbello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700, (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)
- MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515
- One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)
- Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)
- Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7
- Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555
- Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
- Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
- Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 800–877–2520, (Formerly: SmithKline Beecham Clinical Laboratories)
- S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227
- South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276
- Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027
- St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052
- STELRING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438
- Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273
- Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
- US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085
- *The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance
contaminated with a Salmonella serotype that is pathogenic to the target animal for the animal feed.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by November 1, 2010.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft CPG.

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

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–276–9200.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA staff entitled “Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed.” The draft CPG provides guidance for FDA staff regarding the contamination of animal feed and feed ingredients with Salmonella. The draft CPG proposes criteria that should be considered in recommending enforcement action against animal feed or feed ingredients that are adulterated due to the presence of Salmonella. In particular, the draft CPG proposes regulatory action guidance relating to animal feed or feed ingredients that are contaminated with Salmonella and (1) come in direct contact with humans, such as pet food and pet treats, or (2) are contaminated with a Salmonella serotype that is pathogenic to the target animal for which the animal feed is intended. The draft CPG also contains information that may be useful to regulated industry and the public.

FDA is issuing the draft CPG as Level 1 draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency’s current thinking on enforcement recommendations for certain circumstances where animal feed or feed ingredients are contaminated with Salmonella. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the draft CPG. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG at either http://www.fda.gov/ora/compliance_ref/cpg/default.htm or http://www.regulations.gov.


Michael A. Chappell, Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–18873 Filed 7–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0378]

Draft Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for FDA staff entitled “Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed” (the draft CPG). The draft CPG, when finalized, is intended to provide guidance for FDA staff on regulatory policy relating to animal feed or feed ingredients that come in direct contact with humans, such as pet food and pet treats, contaminated with Salmonella and also on regulatory policy relating to animal feed or feed ingredients

recommending enforcement action against animal feed or feed ingredients that are adulterated due to the presence of Salmonella. In particular, the draft CPG proposes regulatory action guidance relating to animal feed or feed ingredients that are contaminated with Salmonella and (1) come in direct contact with humans, such as pet food and pet treats, or (2) are contaminated with a Salmonella serotype that is pathogenic to the target animal for which the animal feed is intended. The draft CPG also contains information that may be useful to regulated industry and the public.

FDA is issuing the draft CPG as Level 1 draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency’s current thinking on enforcement