Dated: March 16, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–6031 Filed 3–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0641]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

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 written comments on the collection of information by April 20, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0578. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments—(OMB Control Number 0910–0578—Extension)

The Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles. Operators may decide to incorporate some or all of the principles presented in the manual into their existing food safety management systems. The recordkeeping practices discussed in the manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: (1) Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and (2) verification (assessing whether the establishment is following its voluntary food safety management system). The manual includes a sample entitled ''Verification Inspection Checklist'' to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: (1) Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); (2) risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); (3) hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); (4) prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); (5) monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); (6) corrective action (records indicating the activities that are completed whenever a critical limit is not met); (7) ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly); and (8) validation (records indicating that scientific and technical information is collected and evaluated to determine if the food safety management system, when properly implemented, effectively controls the hazards).

All recommendations in both manuals are voluntary. For simplicity and to avoid duplicate estimates for operator recordkeeping practices that are discussed in both manuals, the burden for all collection of information recommendations for retail and foodservice operators are estimated together in table 1 of this document, regardless of the manual in which they appear. Collection of information recommendations for regulators in the Regulator's Manual are listed separately in table 2 of this document.

Description of Respondents: The likely respondents to this collection of information are operators and regulators of retail and foodservice establishments.

In the **Federal Register** of December 19, 2008 (73 FR 77721), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR OPERATORS[1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Prerequisite Program Records	100,000[2]	365	36,500,000	0.1	3,650,000
Monitoring Records	100,000[2]	365	36,500,000	0.3	10,950,000
Corrective Action Records	100,000[2]	365	36,500,000	0.1	3,650,000
Ongoing Verification Records (includes calibration records)	100,000[2]	365	36,500,000	0.1	3,650,000
Validation Records	50,000[2]	1	50,000	4	200,000
Annual Burden[3]:					22,100,000
Risk Control Plan	50,000	1	50,000	2	100,000
Monitoring Records	100,000	90	9,000,000	0.3	2,700,000
Corrective Action Records	100,000	90	9,000,000	0.1	900,000
Ongoing Verification Records (includes calibration records)	100,000	90	9,000,000	0.1	900,000
Annual Burden[4]					4,600,000
Total Annual Burden for Operators					26,700,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Annual burden.
[3] Burden for developing and implementing a food safety management system based on the Operator's Manual.
[4] Annual burden for developing and implementing a risk control plan based on the Regulator's Manual.

The burden for these activities may vary among retail and foodservice operators depending on the type and number of products involved, the complexity of an establishment's operation, the nature of the equipment or instruments required to monitor critical control points, and the extent to which an operator uses the Operator's Manual and/or the Regulator's Manual. The estimate does not include collections of information that are a usual and customary part of an operator's normal activities. FDA has established as a goal to have 50,000 (0.05 percent) of the approximately 1 million U.S. retail and foodservice operators implement the recommendations outlined in the 2 manuals. This target figure is used in calculating the burden in tables 1 and 2 of this document because the agency lacks data on how to base an estimate of how many retail and foodservice establishments are likely to use one or more of the manuals to voluntarily implement a comprehensive food safety management system based on HACCP principles or a risk control plan for out-of-control processes identified during an inspection. FDA's estimate of the total number of retail and foodservice establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute, and the National Restaurant Association, respectively.

The hour burden estimates in table 1 of this document for operators who follow the HACCP-based recommendations in the Operator's Manual are based on the estimated average annual information collection burden for mandatory HACCP rules, including seafood HACCP (60 FR 65096 at 65178; December 18, 1995) and juice HACCP (66 FR 6138 at 6202; January 19, 2001). FDA estimates that once the system is in place, the annual frequency of records is based on 365 operating days per year. Assuming there is one recordkeeper per shift of operation, the agency estimates that two recordkeepers per day would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the system. The agency further estimates that validation will be conducted once per year, based on menu or food list changes, changes in distributors, or changes in food preparation processes used. The validation will require a total of 4 labor hours.

The second set of estimates in table 1 of this document shows the annual burden for developing and implementing a risk control plan to control specific out-of-control foodborne illness risk factors identified during an inspection by a State, local, or tribal regulatory authority. If an operator decides to use a risk control plan as recommended in the Regulator's Manual, one person from the establishment is needed to work with the regulator to develop the written plan. FDA estimates that two recordkeepers per day (one recordkeeper for each shift) would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the risk control plan. The estimated duration of implementation for a risk control plan is 90 days, which is the minimum recommended time to achieve long-term behavior change.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS[1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

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

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But, FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Dated: March 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6168 Filed 3–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0136]

Draft Guidance for Industry on Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment; 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 industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' This draft guidance informs industry of FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for treatment of community-acquired bacterial pneumonia (CABP). This draft guidance does not address the development of drugs for other purposes or populations, such as treatment of patients with hospital-acquired pneumonia or ventilator-associated pneumonia. This draft guidance revises the draft guidance for industry entitled ''Community-Acquired Pneumonia-Developing Antimicrobial Drugs for Treatment'' published July 1998.

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 written or electronic comments on the draft guidance by June 18, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Sumathi Nambiar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6232, Silver Spring, MD 20993–0002, 301–796–1400; or

Edward Cox, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, rm. 6212, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' Since FDA published the draft guidance on the development of antimicrobial drugs for the treatment of community-acquired pneumonia in 1998, there have been public discussions regarding clinical trial designs to study CABP, including an FDA–Infectious Disease Society of America (IDSA) workshop and a meeting of the Anti-Infective Drugs Advisory Committee. These discussions have focused on clinical trial designs for CABP and other important issues such as the following:

- Noninferiority versus superiority design
- Justification of an appropriate noninferiority margin
- Classification of severity of illness
- Classification of CABP based on hospitalization (inpatient versus outpatient)
- Enrollment criteria
- Application of appropriate diagnostic criteria, including microbiologic diagnosis
- Use of appropriate definitions of clinical outcomes, including mortality
- Timing of outcome assessments
- Use of prior antibacterial drugs

Important changes from the 1998 draft guidance that are based on these discussions have been incorporated into this revised draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the development of antibacterial drugs for CABP including appropriate clinical trial designs to evaluate drugs for the treatment of CABP. 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