

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section/Title/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(4)(v)/Summary Report of Increased Frequency of Adverse Drug Experience	190	1.58	300	2	600
514.80(b)(5)(i)/Special Drug Experience Report/Form FDA 2301	190	0.13	25	2	50
514.80(b)(5)(ii)/Advertising and Promotional Materials Report/Form FDA 2301	190	2.11	772	2	1,544
514.80(b)(5)(iii)/Distributor's Statement Report/Form FDA 2301	530	0.14	56	2	112
Total					35,177

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

² The reporting burden for § 514.80(b)(4)(iv)(A) is included in the reporting burden for § 514.80(b)(2)(i).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.80(e) ²	530	28.22	19,385	0.5	9,693
514.80(e) ³	530	4.06	2,379	10.35	24,623
Total					34,316

¹ Burden estimates were separated between Form FDA 1932 and Form FDA 2301 to reflect the difference in estimates for "Hours per Respondent" required.

² Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.

³ Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

Forms FDA 1932 and FDA 2301 for this collection of information are currently approved under OMB control number 0910-0012 and will not change due to implementation of this regulation. The reporting and recordkeeping burden estimates in this document are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The total annual response numbers are based on the 2000 fiscal year submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The numbers in tables 1 and 2 of this document are total burden associated with this regulation. Section 514.80(b)(3) and (b)(4)(v) are new information collection requirements over the current requirements.

Dated: April 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Health Resources and Services Administration

HRSA-03-099 Fiscal Year 2003 Competitive Cycle for the Bioterrorism Training and Curriculum Development Program (BTCDP) 93.996

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration announces that cooperative agreement applications will be accepted for the Bioterrorism Training and Curriculum Development Program for Fiscal Year 2003.

Purpose: The Bioterrorism Training and Curriculum Development Program consists of two discrete goals: (1) Provision of Continuing Education for practicing providers; and (2) Curricular Enhancement in health professions schools. Each area requires a separate application for funds.

Cooperative Agreements will be awarded to assist eligible entities to prepare a workforce of healthcare professionals to address the medical consequences of bioterrorism and other public health emergency preparedness and response issues. In this context, "other public health emergencies" includes other forms of terrorism (such as use of chemical, explosive,

incendiary, or nuclear agents against the civilian population) as well as natural disasters and catastrophic accidents. Specifically, the goal of this program is the development of a healthcare workforce that possesses the knowledge, skills and abilities to: (1) Recognize indications of a terrorist event; (2) meet the acute care needs of patients, including pediatric and other vulnerable populations, in a safe and appropriate manner; (3) participate in a coordinated, multidisciplinary response to terrorist events and other public health emergencies; and (4) rapidly and effectively alert the public health system of such an event at the community, State, and national level.

Healthcare professionals provide a pivotal link to their communities. They disseminate accurate, responsible, trustworthy, and timely health related information to the public-at-large. This crucial component of the emergency response network helps to mitigate mortality and morbidity and to preserve public order while using resources effectively and efficiently. These professionals must be provided with the essential information needed to quickly identify a terrorist event; appropriately treat/respond to those in need of acute care; rapidly report such events to the public health authorities at the local, State and national levels, and participate in a coordinated and multidisciplinary response. The ability to meet the population's needs for acute