addresses recordkeeping requirements that are already codified, the guidance documents themselves create no new paperwork burdens. However, the agency acknowledges that, on occasion, the information collection contained in guidance documents is beyond the scope of the regulation. FDA recognizes the need to ensure all potentially new paperwork burdens are identified, and that public comment is sought accordingly.

Regarding electronic recordkeeping, the agency fully met its obligations under the paperwork reduction act in developing and issuing part 11 and received no objections to the rule with respect to paperwork reduction. In fact, extensive discussions were held with industry throughout the development of the rule. FDA believes that the benefits of electronic recordkeeping, especially with regard to paperwork reduction, far outweigh the costs of compliance with part 11 to ensure that the electronic records are trustworthy, reliable, and compatible with FDA's mandate to protect and promote public health.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOP Maintenance (See previous list of 25 SOP's)	4,184	1	4,184	25	104,600
One-time Burden (New Start-up SOP's)[2]	100	25	2,500	20	50,000
211.34	4,184	.25	1,046	.5	523
211.67(c)	4,184	50	209,200	.25	52,300
211.68	4,184	2	8,368	1	8,368
211.68(a)	4,184	10	41,840	.5	20,920
211.68(b)	4,184	5	20,920	.25	5,230
211.72	4,184	.25	1,046	1	1,046
211.80(d)	4,184	.25	1,046	.1	105
211.100(b)	4,184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	.25	262
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
2111.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1,077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This is a one-time burden.

Dated: April 12, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–9636 Filed 4–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–0804]

Rohm and Haas Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Rohm and Haas Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone as a preservative and slimicide in the manufacture of paper and paperboard in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5)(21 U.S.C. 348(b)(5), notice is given that a food additive petition (FAP 9B4645) has been filed by Rohm and Haas Co., 100 Independence

Mall West, Philadelphia, PA 19106. The petition proposes to amend the food additive regulations in § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods and § 176.300 Slimicides to provide for the safe use of 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone as a preservative and slimicide in the manufacture of paper and paperboard for use in contact with food.

The agency has determined under 21 CFR 25.32(q) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 30, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–9674 Filed 4–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Research and Development of Software for Managing Distributed Knowledgebases Consisting of Large Numbers of Objects of Diverse Categories Spanning Administrative, Scientific and Other Knowledge Domains

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute seeks a Cooperative Research and Development Agreement (CRADA) with a software company with demonstrated excellence in the development and deployment of software applications for the enterprise and individuals. NCI has recently developed a powerful but user-friendly computer-based system which enables its users to create, use and share a knowledge base of information consisting of diverse objects related to each other by semantically meaningful links. This system, provisionally called ''KBTool'', can be considered a new class of software application since it is sufficiently different from existing applications. The system provides a knowledge base that is seamless, allowing individuals to store information on a virtually unlimited range of objects and concepts. In addition, dense and informative links between many types of concepts are constructed. The system is extensible so that it is suited for use in distributed systems in which information is shared between users and stored at different physical locations. Because of the power of the system and its relevance to many domains of knowledge and types of applications, the NCI is seeking a commercial partner for its continued development and deployment. The software was originally created to organize and link vast quantities of scientific data; however, NCI predicts that KBTool's functionality will be applicable to a wide variety of fields. The Collaborator must have a demonstrated record of success in privately producing and marketing information resources.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal no later than June 18, 1999. They will then have an additional thirty (30) days to submit a formal proposal.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Holly S. Symonds, Ph.D. (Tel. #301–496–0477, FAX #301–402–2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining patent license(s) needed for participation in the CRADA opportunity may be addressed to John Fahner-Vihtelic, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301–496–7735, ext. 270; FAX 301–402–0220).

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by the NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. The NCI is looking for a CRADA partner to collaborate in the development of the properties of the KBTool data management system. The expected duration of the CRADA would be from one (1) to five (5) years.

KBTool is a data management system and process for efficiently storing and retrieving data. The Experimental Immunology Branch of the NCI has designed KBTool to combine maximum data management flexibility and stability into unified knowledgebase applications. As a result, it has a diverse functionality which can replace users' fragmented world of specialized applications such as contact manager, administrative database, bookmark keeper, and fact finder. Some unique features of this software-based invention are: (1) ability to handle any number of conceptually distinct categories of items (such as people, events, institutions, tasks, concepts, processes, document types); (2) tools for creating relationships between any two or more objects, with the ability to categorize types of relationships and decide which categories they apply to; (3) use of parent-child relationship as a singularly important relationship to organize, view and navigate information; (4) flexibility in adding diverse categories of objects and relationships, while maintaining a simple underlying data structure and programming environment; (5) ability to view complex relationships in flexible and informative ways; (6) tools for managing names which are indispensable for finding the relevant objects; and (7) efficient ways to search information and filter retrievals to limit to relevant information.

The prototype implementation of KBTool is already a highly functional system. For example, it manages information on more than 50,000 ''concepts''. These concepts are classified into more than 200 distinct categories. The 10 most highly represented categories are biased towards biological and software knowledge domains: genes, transcripts, proteins, protein spots; humans, institutions, journals, scientific publications, visuals, software applications, and scientific methods. However, its diversity is reflected in categories such as tasks, events, equipment, accounts, documents, areas of expertise and geographical locations. It has more than 50,000 links between these items; each of which conveys not simply the existence of a relationship, but the character of that relationship. This data is distributed into multiple linked databases. The most remarkable feature of the design of the data engine and knowledge representation is its simplicity and generality.

KBTool was designed to allow the maintenance of a ''fabric'' of information regarding biological systems. It's current implementation can be viewed as the first in a sequence of many steps towards a ''virtual cell'', which allows modeling of the enormous complexity of a human cell. Having taken this first step, NCI would like to solidify the prototype and subsequent steps in the process. Because of the myriad of components in a biological cell, KBTool had to be designed with