seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, FDA no longer includes the text of ICH guidances in the **Federal Register**. Instead, the agency publishes a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances will be left in the original ICH format. The final guidance will be reformatted to conform to the GGP style before publication.

In November 2000, the ICH Steering Committee agreed that an ICH draft guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Drug Products'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

ICH Q1A(R) notes that, if justified, the use of two types of reduced stability study designs (i.e., bracketing and matrixing) can be applied to the testing of new drug substances and products, but ICH Q1A(R) provides no further guidance on the subject. This draft guidance (ICH Q1D) describes the principles for applying bracketing or matrixing in situations where further justification is or is not important. Design factors and other considerations are presented, and potential risks of using reduced designs are discussed. Sample designs are provided as illustrations.

This draft guidance represents the agency's current thinking on reduced stability testing of new drug substances and products. 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 satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by November 26, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23981 Filed 9–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0418]

Solvay Pharmaceuticals, Inc.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new drug applications (NDAs) held by Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062. In 1997, the agency informed Solvay of its intention to assess the validity of data and information in all of Solvay's pending and approved applications. However, Solvay does not intend to conduct validity assessments of the two NDAs named in this notice because the products are no longer marketed. Solvay has agreed to permit FDA to withdraw approval of the applications, thereby waiving its opportunity for a hearing.

DATES: Effective September 25, 2001.

FOR FURTHER INFORMATION CONTACT: David Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: Recently, FDA determined that Solvay submitted untrue statements of material fact in several applications filed with the agency. These findings, along with other information submitted to the agency by Solvay, provided sufficient justification to question the reliability of data in all of Solvay's applications filed with the agency. Solvay was notified in writing of the agency's determinations and its intention to assess the validity of the data and information in all of Solvay's pending and approved applications. The agency offered Solvay the opportunity to permit FDA to withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of any application not undergoing a validity assessment.

Subsequently, in letters dated February 29, 2000, Solvay requested withdrawal under § 314.150(d) of the following NDAs held by Solvay:

NDA 16–782; Lithonate (lithium carbonate tablets USP) 300 milligrams (mg); and

NDA 16–980; Lithotabs (lithium carbonate tablets USP) 300 mg.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority

delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82), approval of the NDAs listed above, and all amendments and supplements thereto, is withdrawn effective September 25, 2001. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action.

Dated: September 17, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–23979 Filed 9–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Assessment of the National Leadership Institute Program and Services

—(OMB No. 0930–0203, Revision)— The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) is conducting an assessment of its National Leadership Institute (NLI). The goal underlying the technical assistance and training opportunities provided through the NLI is to strengthen the competitive position of nonprofit community-based organizations (CBOs) which are essential components of local substance abuse services for the uninsured and under-insured.

Both a process and an impact assessment are being conducted. The process assessment describes the needs faced by CBOs, the types of training and technical assistance that CBOs receive through the NLI, and CBO satisfaction with services. The impact assessment focuses on specific changes made by CBOs in response to NLI recommendations, and improvements in self-rated organizational performance and several organization status measures.

The assessment design for technical assistance is a pre-post-post design that collects identical information from the TA recipient organizations at initiation of NLI contact and again after 12 and 24 months. These time frames are necessary to allow CBOs the opportunity to address NLI technical assistance recommendations and to plan and implement their changes. In addition, the assessment collects satisfaction measures from the TA recipient organization after each technical assistance event and at 12 and 24 months after the initial TA event.

The training component of NLI is also a pre-post-post design. Participants complete a brief questionnaire prior to receiving either onsite or online training, as well as immediately upon completion of the training. Training participants are also sent a 30-day follow-up questionnaire in the mail. With the introduction of online training, the 30-day follow-up may be submitted via e-mail, as well.

Most of the evaluation forms for both TA and training are undergoing minor revisions. The Organizational Self-Assessment and the 12-Month Follow-Up Organizational Self-Assessment will be revised to eliminate some of the items that were confusing to respondents and to capture some key indicators that will be more useful to TA providers and for evaluation purposes. The Activity Summary will be revised to better capture GPRA data and to better record the nature of the recommendations an agency receives from a TA provider. There will not be substantial changes to any of the TA-related satisfaction forms.

The training forms are undergoing minor revisions that include rewording and the addition and/or deletion of questions to tailor the instrument to persons who participate in NLI's online training.

This request is also to extend OMB clearance to 2005 to allow for a continued assessment of the NLI's services. NLI anticipates receiving inquiries from 80 CBOs per year over the next three years, for a total of 240 programs. NLI anticipates receiving requests for technical assistance from 70 CBOs per year over the next three years, for a total of 210 programs. Data collection burden is borne primarily by directors of the CBOs who provide initial contact information (3 minutes), pre- and post-test versions of organizational self-assessments (75 minutes each), satisfaction forms (5 minutes each for 2 types of questionnaires), and activity summaries/telephone interviews (20 minutes). Finally, an estimated 500 individuals will attend NLI onsite training events and/or complete an online training course per year, for a total of 1,500 individuals. These individuals will receive a brief questionnaire prior to the training and satisfaction questionnaires immediately after the training, as well as 30 days after the training (5 minutes each).

The chart below summarizes the estimated total three-year burden and annual average burden.

Form	Number of respondents	Responses per respondent	Hours per response	Total hours
Technical Assistance Recipients				
Initial Contact Form	240	1	.10	24
Organization Self-Assessment	210	[1] 3 (pre-TA and 12 and 24 months post)	1.25	786
Technical Assistance Event Satisfaction	210	2	.08	34