draft guidance provides recommendations to sponsors of new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files or veterinary master files who intend, during the postapproval period, to change the site of manufacture, the scale of manufacture, the equipment, the specifications, and/or the manufacturing process of intermediates in the synthetic pathway leading to the drug substance.

DATES: Written comments on the draft guidance may be submitted by March 31, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cvm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kasturi Srinivasachar, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5376, or David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance defines recommended chemistry, manufacturing and controls tests, and documentation in support of each change. The draft guidance applies to synthetic drug substances and the synthetic steps involved in the preparation of semisynthetic drug substances. It is limited to structurally well-characterized drug substances where impurities can be monitored at the levels recommended. The draft guidance covers changes as follows: (1) Site, scale, and equipment changes involving the synthetic steps up to and including the step that produces the final intermediate, (2) specification changes for raw materials, starting materials, and intermediates, excluding the final intermediate, and (3) manufacturing process changes involving the synthetic steps up to and including the final intermediate. Postapproval changes affecting: (1) Synthetic peptides, (2) oligonucleotides, (3) radiopharmaceuticals, or (4) drug substances derived exclusively by isolation from natural sources or produced by procedures involving biotechnology are not addressed in this document.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on postapproval changes for the manufacture of intermediates in drug substance syntheses. 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 requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31765 Filed 11–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0996]

Draft Guidance for Industry on General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products; 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 ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products.'' This document is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

DATES: Written comments may be submitted on the draft guidance by January 29, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Copies of this guidance may also be obtained by fax from 1–888–CBERFAX or 301–827–3844 or by mail from the CBER Voice Information System at 800–835–4709 or 301–827–1800.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products.'' The guidance is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

In the past few years, the agency has addressed the need for greater information on the use of drugs in the pediatric population. In the **Federal**

Register of December 13, 1994 (59 FR 64240), FDA published a final rule that encouraged manufacturers to provide more information in the labeling on the use of a drug in the pediatric population. The rule recognized several methods of establishing substantial evidence to support pediatric labeling claims, including relying in certain cases on studies carried out in adults. Under the final rule, products may be labeled for pediatric use based on adequate and well-controlled studies in adults together with other information supporting pediatric use (e.g., pharmacokinetic data, safety data, pharmacodynamic data). In the **Federal Register** of August 15, 1997 (62 FR 43899), FDA published a proposed rule that would require new drugs and biological products to be labeled for use in the pediatric population. The enactment of the Food and Drug Modernization Act of 1997 (Pub. L. 105–111) (Modernization Act) on November 21, 1997, further addressed this need by providing incentives to sponsors for conducting pediatric studies (21 U.S.C. 355a). This draft guidance addresses general considerations for conducting PK studies in the pediatric population.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on pediatric pharmacokinetic studies. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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.

Dated: November 19, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31691 Filed 11–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of National Youth Anti-Drug Media Campaign

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes on Drug Abuse of the National Institutes of Health will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

PROPOSED COLLECTION: *Title:* Evaluation of National Youth Anti-Drug Media Campaign. *Type of Information Collection Request:* New. *Need and use of Information Collection:* The White House Office of National Drug Control Policy has transferred funds to NIDA to conduct an independent, scientifically designed and implemented evaluation of the National Youth Anti-Drug Media Campaign, the first prevention campaign to use paid advertising to discourage youth from drug use. The study will assess the outcomes and impact of the national campaign in reducing illegal drug use among children and adolescents.

For this study, two different surveys will be conducted: (1) the National Survey of Parents and Youth, a cross-sectional household survey; and (2) a Longitudinal Study of Parents and Youth in four communities with an ethnographic component. All data will be collected using a combination of computer-assisted personal interviews (CAPI) and audio computer-assisted self-interviews (ACASI). The findings will form the basis of semiannual and annual reports on campaign progress. These reports will provide assistance in improving the national campaign, and will help to establish a rich data base of information about the process involved in changing attitudes and behaviors by the mass media.

Frequency of Response: The National Survey of Parents and Youth will be carried out in 8 waves over a four-year period. Each data collection wave will last 6 months. The Longitudinal Study will be carried out annually over four years. *Affected Public:* Individuals and households. *Type of Respondents:* Children and parents. The annual reporting burden is as follows:

TABLE 1: RESPONDENT AND BURDEN ESTIMATE

Type of respondents	Estimated number of respondents	Estimated number of responses of per respondent	Average burden hours per response	Estimated total burden hours requested	Estimated annualized burden (over 3 years)
National Survey of Youth and Parents					
Screener respondent	225,600	1	.07	15,792	5,264
Youth 9–11	6,600	1	.50	3,300	1,100
Adolescents 12–18	13,800	1	.75	10,350	3,450
Parents	20,700	1	.75	15,525	5,175
Longitudinal Study					
Screener respondent	38,000	1	.07	2,600	887
Youth 9–11	2,150	3	.58	3,741	1,247
Adolescents 12–14	2,150	3	.92	5,934	1,978
Parents	3,500	3	.92	9,660	3,220
Total	312,500		.21	66,962	22,321

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. Because of the sensitivity of collecting data from families in households involving children as young as 9 years old, and