TABLE 1.—LIST OF APPROVAL PMA'S FROM APRIL 24, 1997, THROUGH AUGUST 12, 1998—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P960013/98M–0450	Pacesetter, Inc.	Tendril DX Models 1388 T/K Endocardial, Steroid Eluting Screw-In Pacing Leads and Ventritex Assure AFS Models 7010 T/K Endocardial Steroid Eluting Screw In Pacing Leads	June 20, 1997
P960042/98M–0451	Spectranetics Corp.	12 French Laser Sheath Kit	December 9, 1997
P950009/S002/98M–0251	Neopath, Inc.	Autopap Primary Screening System	May 5, 1998
P960013/98M–0450	St. Jude Medical	Locator Steerable Stylet Model 4036	June 15, 1998
P960042/001/98M–0451	Spectranetics Corp.	12 French Outer Sheath	June 16, 1998
P970062/98M–0507	BMT, Inc.	Genestone 190 Lithotripter	June 24, 1998
P970058/98M–0618	R2 Technology, Inc.	M 1000 Image Checker	June 26, 1998
P960011/98M–0604	Bio-Technology General Corp.	Biolon 1% Sodium Hyaluronate Viscoelastic Surgical Aid Fluid	July 16, 1998
P960018/98M–0619	Healthcare Products Plus, Inc.	The Needlyzer The Needle Destroyer Model ND 2	July 16, 1998
P950005/98M–0678	Cordis Webster, Inc.	Cordis Webster Diagnostic/Ablation Deflectable Tip Catheter	July 22, 1998
P980015/98M–0679	Biomedical Disposal, Inc.	Sharpx Needle Destruction Unit	August 6, 1998
P970040/98M–0715	Lunar	Achilles & Ultrasonometer	June 26, 1998
P970051/98M–0711	Cochlear Corp.	Nucleus 24 Cochlear Implant System	June 25, 1998
P960034/98M–0725	Pharmacia & UpJohn	Cleon Heparin Surface Modified (ASM) Ultraviolet light	August 12, 1998

[1] This means generic name.

Dated: December 15, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–34347 Filed 12–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1020]

Draft Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse To Be Used by the Consumer; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer.'' This draft guidance addresses screening devices sold over-the-counter for testing drugs of abuse. This type of device is intended for use in the home setting as a screening test for any, or any combination, of the following five substances in urine: Amphetamine/methamphetamine, cocaine, cannabinoids, opiates, and phencyclidine.

DATES: Written comments concerning this draft guidance must be received by March 30, 1999.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance entitled ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

Over the last several years, FDA has worked to clarify the regulation of products for use in the home setting intended to screen for drugs of abuse. On September 17, 1997, FDA released for comment a draft guidance document entitled ''Points to Consider for Approval of Home Drugs of Abuse

Screening Kits.'' On September 25, 1997, FDA held an open public meeting of the Clinical Chemistry and Clinical Toxicology Panel (the Panel), an FDA advisory committee, in order to discuss and receive comments on the September 1997 guidance. Based upon comments and recommendations received at this meeting from the Panel, the public, and manufacturers, FDA has revised the September 1997 guidance.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on drugs of abuse home screening kits. 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 applicable statute, regulations, or both. This guidance is not final nor is it in effect at this time. This draft guidance replaces the September 17, 1997, guidance.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 2209 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before March 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 15, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–34346 Filed 12–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Young Drivers Intervention Study

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

PROPOSED COLLECTION:

Title: Young Drivers Intervention Study.

Type of Information Collection Request: New.

Need and Use of Information Collection: The purposes of this study are (1) to determine the impact of parental actions to monitor and control their adolescents' driving behavior on adolescent driving behavior and motor vehicle crashes, and (2) to test the efficacy of educational persuasive communications in promoting parental restriction of their adolescent's risky driving behavior. The specific questions addressed in this study include: (1) Are parents' perceptions about dangers associated with adolescent driving associated with parental involvement in their adolescent's driving experiences? (2) Is a parent-teen driving agreement an effective way of increasing parental involvement and reducing adolescent risky driving? (3) Does increased parental involvement reduce risky driving behaviors and decrease traffic tickets and crashes among adolescents?

A sample of adolescents applying for their learner's permit and one of their parents will be recruited through department of motor vehicles offices and driver's education courses in two states. In each state, 1600 parent-adolescent dyads will be recruited and interviewed four times over the course of the 2-year prospective observational study. During the initial interview, consent, demographic information, and contact information will be obtained. Within two weeks, parents and their adolescents will be interviewed over the telephone. Parents will be asked about their expectations and parenting practices regarding their adolescents' driving behaviors. Adolescents will be asked about their driving practices, their parents' rules and restrictions regarding driving, and other psychosocial variables. These same variables will be assessed again during telephone interviews with both parents and adolescents at six, twelve, and eighteen months intervals. The driving records for each adolescent will be obtained from the state motor vehicle administration and examined at the end of the 24-month period.

Parent-teen dyads will be randomly assigned to the basic information comparison condition or the special-intervention treatment condition. Parents in the comparison condition will receive standard information about the move toward graduated licensing in their state and the high risk related to adolescent driving. Parents in the special intervention will receive personalized educational material in the mail, including a parent-teen driving agreement and an educational videotape. During the 24 month period of the study, dyads will be contacted three more times: (1) when adolescents apply for their provisional/full license, (2) 6 months after provisional/full licensure, and (3) 12 months after provisional/full licensure. At each time, parents and adolescents will be interviewed over the telephone regarding parenting practices related to involvement in and restriction of adolescents' driving experience, and adolescents' driving behaviors.

Frequency of Response: data will be collected 4 times over a two-year period; two times each year for two years.