information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Records; Electronic Signatures—Part 11 (21 CFR Part 11) (OMB Control Number 0910–0303)–Extension

The Food and Drug Administration (FDA) regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically, provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, state or local governments, Federal agencies, and nonprofit institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Record-keepers	Annual Fre-quency of Rec-ordkeeping	Total Annual Records	Hours per Rec-ordkeeper	Total Hours
11.10	2,250	1	2,250	20	45,000
11.30	2,250	1	2,250	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

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

Dated: September 24, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25491 Filed 9–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1651]

Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA.'' This draft guidance is intended to provide recommendations to holders of new animal drug applications (NADA's) and abbreviated new animal drug applications (ANADA's) on how they should report changes to such applications in accordance with proposed amended regulations that are found elsewhere in this issue of the **Federal Register**.

DATES: Written comments should be submitted by December 15, 1999.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments 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 full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Office of New Animal Drug Evaluation (HFV–140), Center for Veterinary Medicine, Food

and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

Section 116 of the Food and Drug Administration Modernization Act (the Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). This section provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such change. Elsewhere in this issue of the **Federal Register**, FDA is proposing to amend its regulations on supplements and other changes to an approved application § 514.8 (21 CFR 514.8) to conform to section 506A of the act.

The purpose of this draft guidance is to provide recommendations to holders of NADA's and ANADA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 514.8. The draft guidance covers recommended reporting categories for postapproval changes for new animal drugs. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, and (6) miscellaneous changes. This draft guidance does not provide recommendations on the specific information that should be developed by an applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product. FDA has published guidances, including the Scale-up and Postapproval Changes (SUPAC) guidances, that provide recommendations on reporting categories and/or the type of information that should be developed by the applicant to validate the effect of the change on the identity, strength, quality, purity, or potency of a product as they may relate to the safety or effectiveness of the product. The draft guidance, which cites proposed § 514.8, will be revised based on public comments and implemented for use as a companion document when § 514.8 is finalized.

This draft guidance represents the agency's current thinking on this subject. 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.

II. Comment

Interested persons may, on or before December 15, 1999, submit to the Dockets Management Branch (address above) written comments regarding the 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. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: June 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–25492 Filed 9–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3025–N]

Medicare Program; Notice of the Implementation of the Medicare Lifestyle Modification Program Demonstration Project

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces our implementation of the Medicare Lifestyle Modification Program Demonstration. Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. Such programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion.

FOR FURTHER INFORMATION CONTACT: Armen Thoumaian, Ph.D. at (410) 786–6672, or Athoumaian@HCFA.GOV.

SUPPLEMENTARY INFORMATION: The purpose of this demonstration is to test the feasibility and effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. This demonstration will test a proven and intensive program designed to reduce or reverse the progression of cardiovascular disease (CAD) of patients at risk for invasive treatment procedures. The demonstration will be conducted over a 4-year period at an estimated 15 sites. Enrollment is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy clinical admission criteria.

We are preparing to expand this demonstration to at least one additional nationwide, multi-site cardiovascular lifestyle modification program. An announcement of this expanded demonstration to solicit interested programs is expected within the next several weeks.

We will conduct an independent evaluation of both demonstrations to compare the short-term and long-term outcomes and costs in providing this type of service for Medicare beneficiaries.

Authority: 42 U.S.C. 1395b–1(a)(1)(G) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 14, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–25416 Filed 9–28–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1058–FN]

RIN 0938–AJ60

Medicare Program; Sustainable Growth Rate for Fiscal Year 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the fiscal year 2000 Sustainable Growth Rate (SGR) for expenditures for physicians' services under the Medicare Supplementary Medical Insurance (Part B) program as required by section 1848(f) of the Social Security Act (the Act). The SGR for fiscal year 2000 is 2.1 percent.

EFFECTIVE DATE: The provisions of the Medicare SGR for fiscal year 2000 contained in this notice are effective on October 1, 1999.