Respondents	Number of respondents	Number of responses per respondent	Average burden response/ (in hrs.)	Total burden (in hrs.)
Manual form project areas	17	4	2	136
Scan form project areas	48	4	.25	48
Total	65			184

Dated: March 9, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–6486 Filed 3–15–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0222]

Decision in Washington Legal Foundation v. Henney

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: In the **Federal Register** of August 12, 1999 (64 FR 44025), the Food and Drug Administration (FDA) published in its entirety an order entitled ''Final Amended Order Granting Summary Judgment and Permanent Injunction.'' The order was entered by the United States District Court for the District of Columbia in *Washington Legal Foundation* v. *Henney*, 56 F. Supp. 2d 81 (1999). The Court of Appeals subsequently vacated the district court decision and injunction (and earlier decisions and injunctions) insofar as they declared unconstitutional (1) Statutory provisions concerning the dissemination by manufacturers of certain written materials concerning new uses of approved products (21 U.S.C. 360aaa *et seq.*), and (2) an FDA guidance document concerning certain industry-supported scientific and educational activities known generally as industry-supported continuing medical education or ''CME.'' *Washington Legal Foundation* v. *Henney*, No. 99–5304, 2000 WL 122099, slip op. (D.C. Cir. Feb. 11, 2000). Consequently, these statutory provisions now constitute a ''safe harbor'' for manufacturers that comply with them; the CME guidance document details how the agency intends to exercise its enforcement discretion. FDA, consistent with its longstanding interpretation of the laws it administers, may proceed, in the context of case-by-case enforcement, to determine from a manufacturer's written materials and activities how it intends that its products be used. The Court of Appeals also recognized that if the agency brings an enforcement action, a manufacturer may raise a First Amendment defense.

FOR FURTHER INFORMATION CONTACT:

Regarding biological products and devices regulated by the Center for Biologics Evaluation and Research: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6190.

Regarding human drug products: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828.

Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), as amended, generally prohibits the manufacturer of a new drug or medical device [1] from distributing a product in interstate commerce for any intended use that FDA has not approved as safe and effective. The intended use or uses of a drug or device may be set forth in, among other things, its label or ''labeling,'' which includes written, printed, or graphic matter affixed to or ''accompanying'' the product. See 21 U.S.C. 321(m); 21 CFR 202.1(l)(2); see also 21 CFR 201.128, 801.4. The intended use or uses of a drug or device may also be determined from advertisements, promotional material, oral statements by the product's manufacturer or its representatives, and any other relevant source. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980); see also 21 CFR 201.128 and 801.4.

When FDA approves a drug or medical device, the agency approves the product for each use set out in the product's approved labeling. A use that FDA approves is thus sometimes referred to as an ''approved'' or ''labeled'' use. A use that does not appear in the labeling is not approved as safe and effective by FDA and is known as an ''unapproved'' or ''off-label'' use. In this notice, such a use is referred to as a ''new use.''

A central feature of the FDCA is that it generally prohibits interstate commerce in new drugs and devices for ''new uses.'' In particular, the statute provides that ''[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [21 U.S.C. § 355(b) or (j)] is effective with respect to such drug.'' 21 U.S.C. 355(a); see 21 U.S.C. 331(d). Such an application must identify the particular use or uses to which the new drug will be put, and an approval of such an application for interstate distribution can become effective only with respect to such use(s). See 21 U.S.C. 355(b), (d), (j). Thus, an approved new drug that is marketed for a ''new use'' becomes an unapproved new drug with respect to that use.

An approved new drug that is marketed for a ''new use'' is also ''misbranded'' under the FDCA, because the labeling of such a drug would not include ''adequate directions for use.'' 21 U.S.C. 352(f); see *United States* v. *Articles of Drug * * * Rucker Pharmacal Co.,* 625 F.2d 665, 673 (5th Cir. 1980). Similarly, a medical device that is distributed for a ''new use'' is ''adulterated,'' see 21 U.S.C. 351(f), and ''misbranded,'' see 21 U.S.C. 352(f). An adulterated or misbranded product is prohibited from distribution in interstate commerce (21 U.S.C. 331(a), (k)), as is a drug that is marketed for a ''new use'' (21 U.S.C. 331(d)).

An approved new drug that is marketed for a ''new use'' may be seized (because it is an unapproved new drug with respect to that use), as may an adulterated or misbranded new drug or device (21 U.S.C. 334), and the government may seek an injunction against, or criminal prosecution of,

[1] For purposes of this notice, the terms ''drug or medical device'' include biologic products regulated under section 351(a) of the Pubic Health Service Act.

those responsible for introducing such a product into commerce (21 U.S.C. 332, 333).

Section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA or section 401), 21 U.S.C. 360aaa *et seq.*, amended the FDCA. It describes certain conditions under which a drug or device manufacturer may choose to disseminate to physicians and other health care practitioners certain written materials discussing a ''new use'' of its product. If those conditions are met, the government may not use that dissemination as evidence of the manufacturer's intent that its product be used for a new use. See 21 U.S.C. 360aaa-6(b). If section 401 did not exist, the government could use such dissemination as evidence in establishing a manufacturer's illegal distribution of a new drug or device for a ''new use,'' and in establishing that the product is misbranded or, in the case of a device, adulterated as well as misbranded.

Prior to FDAMA, FDA articulated its policy concerning the promotion of ''new uses'' in three guidance documents. FDAMA and its implementing regulations superseded the two guidance documents that addressed the dissemination of written ''new use'' information (reprints and reference texts) by drug and medical device manufacturers. See 61 FR 52800–52801 (October 8, 1996). FDAMA does not affect the third guidance document (the CME guidance document), which identifies 12 factors that the agency will consider in determining whether a manufacturer, through its support of scientific and educational activities, evidenced a ''new use'' of its drugs or devices. See 62 FR 64093–64100 (December 3, 1997).

Washington Legal Foundation presented a First Amendment challenge to section 401 and the three guidance documents. The district court issued orders declaring FDAMA, its implementing regulations, and the guidance documents unconstitutional. Among other things, the district court, with a number of qualifications, enjoined FDA from ''in any way * * * limit[ing] any pharmaceutical or medical device manufacturer'' from ''disseminating'' specified journal articles or medical texts and from ''suggesting content or speakers'' to an ''independent program provider'' in connection with a seminar or symposium funded by the manufacturer. See *Washington Legal Foundation* v. *Henney*, 56 F. Supp. 2d 81, 88–89 (D.D.C. 1999);*Washington Legal Foundation* v. *Friedman*, 36 F. Supp. 2d 16, 18–19 (D.D.C. 1999); *Washington Legal Foundation* v. *Friedman*, 13 F. Supp. 2d 51, 74–75 (D.D.C. 1998).

On February 11, 2000, the Court of Appeals for the District of Columbia Circuit vacated the district court's decisions and injunctions insofar as they declared section 401 and the CME guidance document unconstitutional. See slip op. at 10. (The other two guidance documents, pertaining to the dissemination of certain written materials about ''new uses,'' had been superseded by FDAMA and its implementing regulations and were not at issue in the Court of Appeals.)

The D.C. Circuit's decision was based on its conclusion that there is no case or controversy to provide a basis for WLF's facial First Amendment challenge. In reaching that conclusion, the court relied on the government's interpretation that (1) Section 401 provides a '''safe harbor' ensuring that certain forms of conduct [will] not be used against manufacturers in misbranding and 'intended use' enforcement actions'' based on pre-FDAMA enforcement authority (slip op. at 8), discussed above, and (2) neither FDAMA nor the CME Guidance Document ''independently authorizes the FDA to prohibit or sanction speech'' (id.). Put another way, if a manufacturer follows the provisions of FDAMA and its implementing regulations (21 CFR part 99), including, but not limited to, its provision concerning the submission of a supplemental application for FDA approval of a ''new use,'' FDA may not use the information disseminated by the manufacturer as evidence that the product is intended to be used for a ''new use.'' If a manufacturer proceeds under section 401 and its implementing regulations but does not comply, FDA may seek to enforce compliance through an injunction action under the FDCA to halt a violation of section 301(z). If a manufacturer does not proceed under section 401, that failure does not constitute an independent violation of law.

FDA traditionally has recognized the important public policy reasons to permit industry support for the full exchange of views in scientific and educational discussions, including discussions of ''new uses.'' FDA has distinguished between those activities supported by manufacturers that are nonpromotional and otherwise independent from the substantive influence of the supporting manufacturer and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting manufacturer and nonpromotional have not been treated as labeling or advertising, and have not been subjected to the agency's regulatory scrutiny. Under the CME guidance document, FDA does not expect to treat industry-supported CME any differently than it traditionally has done. If a manufacturer does not follow the CME guidance document, that, by itself, is not an independent violation of law. Slip op. at 8.

Plaintiff Washington Legal Foundation (WLF) expressly agreed that FDA may proceed on a case-by-case basis under pre-FDAMA enforcement authority. See e.g., *Washington Legal Foundation* v. *Henney*, No. 99–5304, Transcript of Oral Argument, January 10, 2000 (TR.) at 43, 58, 75; see *Washington Legal Foundation* v. *Henney*, slip op. at 7, 8, and 9. Nonetheless, WLF urged the D.C. Circuit to reach the merits of the district court's decisions and injunctions on the ground that FDA ''will prosecute manufacturers for violating a normative standard'' set forth in FDAMA or the CME Guidance Document. Slip op. at 9. The appellate court declined, finding that there was no constitutional controversy between the parties that remained to be resolved and that ruling on the constitutionality of a hypothetical interpretation of the statute would be inappropriate. Id. at 10. In vacating the district court's decisions and injunctions insofar as they declared FDAMA and the CME Guidance Document unconstitutional, the D.C. Circuit noted that a manufacturer may, of course, argue that FDA's use of the manufacturer's promotion of a ''new use'' as evidence in a particular enforcement action violates the First Amendment. Slip op. at 9, n. 6.

In sum, then, FDAMA and its implementing regulations constitute a ''safe harbor'' for a manufacturer that complies with them before and while disseminating journal articles and reference texts about ''new uses'' of approved products. If a manufacturer does not comply, FDA may bring an enforcement action under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is intended for a ''new use.'' Manufacturers that support CME may wish to become familiar with the CME guidance document, which details the factors FDA intends to take into account in exercising its enforcement discretion in relation to industry-supported scientific and educational activities. The CME guidance document, however, does not itself have the force and effect of law.

References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *Washington Legal Foundation* v. *Henney*, No. 99–5304, 2000 WL 122099, slip op. (D.C. Cir. February 11, 2000).

2. *Washington Legal Foundation* v. *Henney*, No. 99–5304, transcript of oral argument, January 10, 2000.

Dated: March 9, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 00–6422 Filed 3–10–00; 4:15 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–3427]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report and Supporting Regulations in 42 CFR 405.2100—405.2184; *Form No.;* HCFA–3427 (OMB# 0938–0360); *Use;* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities, Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 3740; *Total Annual Responses:* 675; *Total Annual Hours:* 1626.25.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 28, 2000.

John P. Burke III,

Reports Clearance Officer, HCFA Office of Information Services Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–6523 Filed 3–15–00; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Study Regarding Shortages of Licensed Pharmacists

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The ''Healthcare Research and Quality Act of 1999'', enacted on December 6, 1999, requires the Department of Health and Human Services (HHS) to ''conduct a study to determine whether and to what extent there is a shortage of licensed pharmacists.'' The Department will include in this study a summary of comments from interested public and private entities. The Department invites all interested public and private entities to submit comments on specific issues, including data and studies supporting their comments.

DATES: Comments must be submitted by May 1, 2000.

ADDRESSES: Address all comments concerning this notice to Vincent C. Rogers, D.D.S., M.P.H., Associate Administrator, Bureau of Health Professions, Health Resources and Services Administration, Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: On December 6, 1999, Congress enacted the Healthcare Research and Quality Act of 1999, Pub. L. 106–129, to amend title IX of the Public Health Service Act by revising and extending the Agency for Healthcare Policy and Research (now referred to as the Agency for Healthcare Research and Quality). Section 5 of Pub. L. 106–129 requires the Secretary of Health and Human Services (HHS), through the appropriate agencies of the Public Health Service, to conduct a study ''to determine whether and to what extent there is a shortage of licensed pharmacists' and to report back to Congress in one year after the date of enactment of the Act on its findings.

A number of associations, such as the National Association of Chain Drug Stores, have been voicing concerns that a shortage of pharmacists in some areas of the country might create a major health crisis. HHS invites comments from public and private sources on the following topics related to pharmacy shortages. Please address your comments by number as indicated below. You need not address all topics.

1. Shortage of pharmacists; for example, vacancy rates for pharmacists' jobs over time, existing documentation of delayed store openings or reduction in store hours, existing documentation of signing bonuses and other hiring incentives, and increases in wages;

2. Difficulties that communities may be experiencing in accessing pharmacy services. HHS is particularly interested in difficulties confronting those in rural or underserved areas, services for the elderly, and other evidence of unmet needs due to a shortage of pharmacists;

3. How pharmacies and employers are addressing a shortage of pharmacists;.

4. The use of technicians, and State laws governing ratios of pharmacists to technicians, and limitations on the functions technicians are permitted to perform, and any requirements for technician certification;

5. The impact of the growth of managed care and third-party coverage of prescriptions on pharmacy practice;