This estimate is based on the average number of new color additive petitions received in 1997 and 1998. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for the number of respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of two Category A and three Category B color additive petitions are expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of five color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to $14,200 (2 x $2,600 + 3 x $3,000 listing fees = $14,200).

Dated: April 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8954 Filed 4–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0297]

Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 19, 1999 (64 FR 13587). The document announced an opportunity for public comment on a draft guidance entitled ''Formal Dispute Resolution; Appeals Above the Division Level.'' The notice was published with two inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–6749, appearing on page 13587 in the **Federal Register** of Friday, March 19, 1999, the following corrections are made:

1. On page 13587, in the first column, under the **DATES** caption, the last sentence is corrected to read ''Written comments on the information collection provisions must be submitted to the Dockets Management Branch (address below) by May 19, 1999. All comments should be identified with the docket number found in brackets in the heading of this document.''

2. On page 13589, in first column, the last paragraph of the document is removed.

Dated: April 6, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8997 Filed 4–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 19, 1999 (64 FR 13591). The document announced an opportunity for public comment on a draft guidance entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' The notice was published with two inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–6748, appearing on page 13591 in the **Federal Register** of Friday, March 19, 1999, the following corrections are made:

1. On page 13591, in the third column, under the **DATES** caption, after the last sentence two sentences are added to read ''Written comments on the information collection provisions must be submitted to the Dockets Management Branch (address below) by May 19, 1999. All comments should be identified with the docket number found in brackets in the heading of this document.''

2. On page 13594, in the first column, the last paragraph of the document is removed.

Dated: April 6, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8998 Filed 4–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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: Medicare Participating Physician or Supplier Agreement, HCFA–460;

Form No.: HCFA–460 (OMB# 0938–0373);

Use: The HCFA–460 is completed by nonparticipating physicians and

supplier if they choose to participate in Medicare Part B. By signing the agreement, the physician or supplier agrees to take assignment on all Medicare claims. To take assignment means to accept the Medicare allowed amount as payment in full for the services they furnish and to charge the beneficiary no more than the deductible and coinsurance for the covered service. In exchange for signing the agreement, the physician or supplier receives a significant number of program benefits not available to nonparticipating physicians and suppliers. The information is needed to know to whom to provide these benefits.;

Frequency: Once, unless re-enrolled;

Affected Public: Business or other for-profit, and Individuals or Households;

Number of Respondents: 45,000;

Total Annual Responses: 45,000;

Total Annual Hours: 11,250.

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: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 31, 1999.

John P. Burke III,

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

[FR Doc. 99–8979 Filed 4–9–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 64 FR 8396, dated February 19, 1999) is amended to reflect the restructuring of the Division of Public Health Surveillance and Informatics, Epidemiology Program Office (EPO), Centers for Disease Control and Prevention (CDC).

Section C–B, Organization and Functions, is hereby amended as follows:

Delete the functional statement for the *Division of Public Health Surveillance and Informatics (CB5)* and insert the following:

(1) Collects, performs analyses, and disseminates public health surveillance information; (2) manages and operates the National Electronic Telecommunications System for Surveillance (NETSS), the National Notifiable Diseases Surveillance System (NNDSS), and the 121 Cities Mortality Reporting System; plans, coordinates, and produces tables, graphs, maps, and figures for the ''Annual Morbidity and Mortality Weekly Report (MMWR) Summary of Notifiable Diseases, U.S.'' and produces MMWR tables from NNDSS; (3) coordinates, develops, implements, and supports CDC-wide public health information systems, including informational and communications applications, directly, as well as in collaboration with other Centers/Institute/Offices (CIOs); (4) develops improved surveillance and public health informatics methods; (5) provides consultation, technical assistance, and training on public health surveillance and health information systems to CDC and to other agencies and domestic and international organizations; (6) coordinates activities of the CDC Surveillance Coordination Group; (7) provides policy and staff support for CDC's Health Information and Surveillance Systems Board; (8) coordinates a CDC-wide initiative aimed at building State and local capacity to perform the core public health function of assessment and use of data for policy development and assurance; (9) provides program support for the development and administration of a CDC training effort in public health informatics; and (10) provides guidance and supervision to EIS Officers and Preventive Medicine Residents assigned to the Division.

Delete the functional statement for the *Office of the Director (CB51)* and insert the following:

(1) Provides leadership and overall direction for the Division; (2) provides leadership and guidance on policy, program planning, program management, and operations; (3) establishes Division goals, objectives, and priorities; (4) monitors progress in implementation of projects and achievement of objectives; (5) provides management, administrative, and support services, and coordinates with appropriate EPO offices on program and administrative matters; (6) provides liaison with other CDC organizations, other governmental agencies, international organizations, the Council of State and Territorial Epidemiologists, and other constituent groups and partners; (7) provides leadership and direction, in collaboration with other CIOs, in the planning and development of computer software for use in surveillance and epidemiology, including testing and revising computer programs; (8) disseminates software for use by public health professionals; (9) plans, allocates, and monitors resources; (10) provides scientific leadership and guidance to the Division to assure highest scientific quality and ethical standards; (11) serves as the Executive Secretariat for CDC's Health Information and Surveillance Systems Board; (12) provides policy support to the Board, including coordination of the activities of the Board's subcommittees and work groups; (13) provides technical assistance, consultation, and guidance to the Board, CDC programs, and constituents on issues related to public health surveillance and health information systems and the Internet; and (14) plans and coordinates the activities of the CDC Surveillance Coordination Group.

Delete in their entirety the title and functional statement for the *Public Health Information Systems Branch (CB53)* and insert the following:

Applied Sciences Branch (CB54). (1) Provides scientific and epidemiologic leadership and direction in public health surveillance and health information systems to CDC and to other agencies and domestic and international organizations; (2) researches and develops new and innovative approaches to the use of technology in surveillance activities; (3) provides guidelines for development, evaluation, and integration of NETSS and other CDC surveillance systems; (4) promotes the dissemination and use of surveillance data; (5) evaluates applicability of outside standards and standard vocabularies to CDC data needs; (6) provides guidance and supervision to EIS Officers, Preventive Medicine Residents, and Public Health Practice Specialists; (7) coordinates a CDC-wide initiative aimed at building