effect of the present requirement is therefore negligible, and the cost of the requirement, both to industry and government, can no longer be justified.

Accordingly, CDC is seeking public comment on its proposal to rescind the requirement for certification of used tire casings from Asia prior to entry into the United States. Comments are sought for thirty (30) days, after which CDC will publish in the **Federal Register** a notice and effective date of action.

Dated: April 6, 1999.

Joseph R. Carter,

Acting Associate Director of Management and Operation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–8987 Filed 4–9–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0670]

Agency Information Collection Activities: Proposed Collection; Comment Request; Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the approval and labeling of color additives.

DATES: Submit written comments on the information collection requirements by June 8, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of 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.

Labeling requirements for color additives (other than hair dyes)—21 CFR 70.25 and Petitions—21 CFR 71.1 (OMB Control Number 0910–0185—Extension)

Description: Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Pub. L. 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, the number of new color additives approved would decrease.

FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Description of Respondents: Business or other for profit.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Hours per Response	Total Hours	Total Operating & Maintenance Costs
70.25	5	1	5			
71.1	5	1	5	1,866	9,330	$14,200
Total	5		5		9,330	$14,200

[1] There are no capital costs associated with this collection of information.

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