concentration computed from the regression equation (Equation 1) which is different from its actual concentration by a factor of 10% can be excluded from the calibration curve. Up to two concentrations may be excluded, but caution should be used in eliminating values, since bias may be increased in the calibration curve. If an outlier value is eliminated, its duplicate value must also be discarded to avoid producing a new bias. All unknowns must fall within the calibration curve; therefore, duplicate values excluded at either end of the calibration curve will restrict the useful range of the assay.

C. Quality Control Pools and Run Rejection Rules

The mean estimated nicotine concentration in a pool should be compared with the established limits for that pool based on at least 20 consecutive runs. An analytical run should be accepted or rejected based upon the following set of rules adapted from Westgard et al. (1981).

1. When the mean of one QC pool exceeds the limit of $\bar{x} \pm 3$ standard deviations (SD), then the run is rejected as out of control. Here, $\bar{x}$ and SD represent the overall mean and standard deviation of all estimated nicotine concentrations for a particular pool in the runs which were used to establish the control limits.

2. When the mean nicotine concentrations in two QC pools in the same run exceed the same direction, then the run must be rejected. The same direction is the condition in which both pools exceed either the $\bar{x} + 2$ SD or the $\bar{x}$–2 SD limits.

3. When the mean nicotine concentrations in one or two QC pools exceed their $\bar{x} + 2$ SD limits in the same direction in two consecutive runs, then both runs must be rejected.

4. When the mean nicotine concentrations in two QC pools are different by more than a total of 4 SD, then the run must be rejected. This condition may occur, for example, when one QC pool is 2 SD greater than the mean, and another is 2 SD less than the mean.

Endnotes

The comments and notes listed below can be described as Good Laboratory Practice guidelines; they are described in detail in this protocol to ensure minimal interlaboratory variability in the determination of nicotine, total moisture, and pH in smokeless tobacco.

[1] This protocol assumes that the testing facility will implement and maintain a stringent Quality Assurance/Quality Control program to include, but not be limited to, regular interlaboratory comparisons, routine testing of random blank samples, determination of the quality and purity of purchased products, and proper storage and handling of all reagents and samples.

[2] When a specific product or instrument is listed, it is the product or instrument that was used in the development of this method. Equivalent products or instruments may also be used. The use of company or product name(s) is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention.

[3] All chemicals, solvents, and gases are to be of the highest purity.

[4] Companies must ensure that the purity of the nicotine base is certified by the vendor and that the chemical is properly stored. However, nicotine base oxidizes with storage, as reflected by the liquid turning brown. If oxidation has occurred, the nicotine base should be distilled prior to use in making a standard solution.

[5] Horizontal shaking will allow more intimate contact of this three phase extraction. There is a minimal dead volume in the tube due to the large sample size and extraction volume. This necessitates horizontal shaking.

[6] If linear shaker is not available, a wrist action shaker using 250 mL stoppered Erlenmeyer flasks can be substituted. Values for nicotine are equivalent to those obtained from the linear shaker.

[7] After installing a new column, condition the column by injecting a tobacco sample extract on the column, using the described column conditions. Injections should be repeated until areas of IS and nicotine are reproducible. This will require approximately four injections. Recondition column when instrument has been used infrequently and after replacing glass liner.

[8] Glass liner and septum should be replaced after every 100 injections.

[9] Most older instruments operate at constant pressure. To reduce confusion, it is suggested that the carrier gas flow through the column be measured at the initial column temperature.

[10] The testing facility must ensure that samples are obtained through the use of a survey design protocol for sampling ''at one point in time'' at the factory or warehouse. The survey design protocol must address short-, medium-and long-term product variability (e.g., variability over time and from contai ner to container of the tobacco product) as defined by ISO Protocol 8243, Annex C. Information accompanying results for each sample should include, but not be limited to:

1. For each product—manufacturer and variety (including brand families and brand variations) and brand name (e.g., Skoal Bandits, Skoal Long Cut Cherry, Skoal Long Cut Wintergreen, etc.) information.

2. Product ''category,'' e.g., loose leaf, plug, twist, dry snuff, moist snuff, etc.

3. Lot number.

4. Lot size.

5. Number of randomly sampled, sealed, packaged (so as to be representative of the product that is sold to the public) smokeless tobacco products selected per lot (sampling fraction) for nicotine, moisture, and pH determination.

6. Documentation of method used for random sample selection.

7. ''Age'' of product when received by testing facility and storage conditions prior to analysis.

[11] Use non-glass 10 mL repipette for transferring NaOH solution.

[12] Use 50 mL repipette for transferring MTBE.

[13] For dry snuff, use 0.500 ± 0.010 gram sample.

[14] The testing facility is referred to ISO Procedure 8243 for a discussion of sample size and the effect of variability on the precision of the mean of the sample (ISO 8243, 1991).

[15] When analyzing new smokeless tobacco products, extract product without IS to determine if any components co-elute with the IS or impurities in the IS. This interference could artificially lower calculated values for nicotine.

[16] The calculated nicotine values for *all* samples must fall within the low and high nicotine values used for the calibration curve. If not, prepare a fresh nicotine standard solution and an appropriate series of standard nicotine dilutions. Determine the detector response for each standard using chromatographic conditions described in I.E.

[17] The method is a modification of AOAC Method 966.02 (1990) in that the ground tobacco passes through a 4 mm screen rather than a 1 mm screen.

[18] When drying samples, do not dry different products (e.g., wet snuff, dry snuff, loose leaf) in the oven at the same time since this will produce errors in the moisture determinations.

References

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[FR Doc. 97–11344 Filed 5–1–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Abuse Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on June 9 and 10, 1997, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn—Bethesda, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers or John Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 9, 1997, the committee will discuss ways in which the labeling for smoking cessation products could be made more clinically useful. Public response to this topic is solicited. Please submit your response to Docket No. 97N–0149, entitled ''Reevaluation of Labeling of Smoking Cessation Products,'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In order for comments to be summarized and sent to the Drug Abuse Advisory Committee prior to the June 9, 1997, meeting, they must be received by Dockets Management Branch by May 13, 1997. The docket will remain open for additional comments until July 11, 1997. On June 10, 1997, the committee will discuss topics in clinical trial design for medications used to treat cocaine abuse.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 27, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 27, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–11442 Filed 5–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (**Federal Register**, Vol. 59, No. 60, pp. 14628–14662, dated Tuesday, March 29, 1994, and subsequent thereafter) is amended to reflect changes to the structure of HCFA.

HCFA has reorganized the way it operates for the following reasons: Growth of managed care, changes in the Federal/State relationship, and movement to a Medicare Transaction System environment. The Centers/Offices are functionally grouped to support beneficiaries and be more responsive to major changes in the health care market.

The specific amendments to Part F are described below:

• *Section F.10.A.5. (Organization) is amended to read as follows:*

1. Press Office (FAE)
2. Office of Legislation (FAF)
3. Office of Internal Customer Support (FAH)
4. Office of Equal Opportunity and Civil Rights (FAJ)
5. Office of Strategic Planning (FAK)
6. Office of Communications and Operations Support (FAL)
7. Office of Clinical Standards and Quality (FAM)
8. Office of Financial Management (FAN)
9. Office of Information Services (FAP)
10. Center for Beneficiary Services (FAQ)
11. Center for Health Plans and Providers (FAR)
12. Center for Medicaid and State Operations (FAS)
13. Consortium #1 (FAU)
14. Consortium #2 (FAV)
15. Consortium #3 (FAW)
16. Consortium #4 (FAX)

• *Section F.20.A.5. (Functions) is amended to read as follows:*

1. Press Office (FAE)

• Serves as the focal point for the Agency to the news media.

• Serves as senior counsel to the Administrator in all activities related to the media. Provides consultation, advice, and training to the Agency's senior staff with respect to relations with the news media.

• Develops and executes strategies to further the Agency's relationship and dealings with the media. Maintains a broad based knowledge of the Agency's structure, responsibilities, mission, goals, programs, and initiatives in order to provide or arrange for rapid and accurate response to news media needs.

• Prepares and edits appropriate materials about the Agency, its policies, actions and findings, and provides them to the public through the print and broadcast media. Develops and directs media relations' strategies for the Agency.

• Responds to inquiries from a broad variety of news media, including major newspapers, national television and radio networks, national news magazines, local newspapers and radio and television stations, publications directed toward the Agency's beneficiary populations, and newsletters serving the health care industry.

• Manages press inquiries, coordinates sensitive press issues, and develops policies and procedures for how press and media inquiries are handled.

• Arranges formal interviews for journalists with the Agency's Administrator or other appropriate senior Agency staff; identifies for interviewees the issues to be addressed, and prepares or obtains background materials as needed.

• For significant Agency initiatives, issues media advisories and arranges press conferences as appropriate; coordinates material and personnel as necessary.

• Serves as liaison with the Department of Health and Human Services and White House press offices.

2. Office of Legislation (FAF)

• Provides leadership and executive direction within the Agency for legislative planning to address the Administration's agenda.

• Tracks, evaluates and develops provisions of annual legislative proposals for Medicare, Medicaid, Clinical Laboratory Improvement Act (CLIA), Health Insurance Portability and Accountability Act (HIPAA) and related statutes affecting health care financing