The methodology (''Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products'') is intended to provide standardized measurement of nicotine, total moisture, and pH in smokeless tobacco products. This information should be submitted in the prescribed format. In addition, we ask that companies provide an electronic copy of this information on a floppy disk or CD–ROM.

Background

In 1989, the smokeless industry submitted a business review letter to the Department of Justice (DOJ), in accordance with 28 CFR 50.6. This letter requested approval of a collaborative industry effort to determine standard nicotine reporting. In January 1993, DOJ extended permission to the smokeless industry to begin the development of uniform methods for analyzing smokeless tobacco products for nicotine or moisture content. The first meeting of the work group, which represented the ten major domestic manufacturers of smokeless tobacco, was convened on July 7, 1993. After a series of meetings of the joint industry work group, a standard methodology was approved by the work group and submitted to OSH for approval. The protocol was revised by OSH based on individual comments received from peer reviewers and the Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, CDC. There are no costs to respondents.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Tobacco Manufacturers	11	1	1,706	18,766
Total				18,766

Dated: October 25, 2001.

Nancy E. Cheal,

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

[FR Doc. 01–27529 Filed 11–1–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9012–NC]

Medicare and Medicaid Programs; Plan to Create an Open and Responsive Federal Agency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces our efforts to enhance our openness and responsiveness to all of our constituencies including Medicare and Medicaid beneficiaries and other individuals involved in their care, physicians, nurses, other health care providers, advocacy associations, and industry trade associations. We are making structural changes in the way we do business to build in processes that will enhance our ability to be responsive. This notice invites comments on our efforts to create an open and responsive agency.

We are proposing to issue quarterly provider updates that list provider-oriented regulatory documents and program instructions. We plan to release the quarterly provider update to provider associations first as a pilot and, at a later time, publish subsequent provider updates on our Web site on the first business day of each calendar quarter.

We are accepting comments about concerns or suggestions for improving our agency. We are particularly interested in specific suggestions on how we can improve our efforts to create an open responsiveness to better address the needs and concerns of all of our constituencies. We are not placing any time constraints for receipt of public comments.

ADDRESSES: In commenting, please refer to file code CMS–9012–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9012–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anthony Mazzarella, (410) 786–7501.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. In order to review public comments, you *must* schedule an appointment by calling (410) 786–7197. To obtain entry to our facility, you *must* have a photo identification (preferably a driver's license).

I. Background

Our mission is to serve Medicare and Medicaid beneficiaries by assuring quality health care security for beneficiaries. In keeping with our mission, we are committed to reforming and strengthening our agency by creating an open responsiveness to the needs and concerns of all of our constituencies including Medicare and Medicaid beneficiaries and individuals involved in their care, physicians, nurses, other health care providers, advocacy associations, and industry trade associations.

II. Plan To Create an Open, Responsive Agency

We want to be a reliable Federal agency; one that is open and responsive to the needs of all of our constituencies. In our effort to enhance our responsiveness to Medicare and Medicaid beneficiaries and their health care providers, we are making structural changes in the way we do business to build in processes that enhance our ability to create an open and responsive Agency. We plan to focus on working openly with our stakeholders, soliciting their individual input and feedback, responding to requests for information in a more timely manner, and issuing a

quarterly provider update of all changes to Medicare regulations and instructions that affect providers.

Because our agency focus is to be open and responsive, we are creating mechanisms that will give our employees a greater opportunity to receive and act on feedback from our constituencies. First, we are establishing a series of open listening forums across the country to be chaired by our senior staff, so that we can hear directly from our constituencies about the impact that our regulations, policies, and programs have on them. We want to hear the concerns and individual suggestions for improvement from physicians and other health care providers, from the people who deal with us in communities and facilities from day to day, and from seniors who rely upon Medicare and Medicaid for their health care needs.

Second, we are creating open door listening forums chaired by our senior staff, and made up of our employees, to serve as principal points of contact for beneficiary and provider groups. Our goal in working with these groups is to build stronger relationships, improve their understanding of CMS, and generate ideas for program improvements and reform, as well as ideas about how we can better serve our beneficiaries. Individual senior staff members will serve as the primary contacts for the following stakeholders to bring issues and ideas about our programs and policies:

- Physicians.
- Hospitals.
- Rural providers.
- Nursing homes.
- Medicare+Choice organizations and other health plans.
- Nurses and allied healthcare professionals.
- Home health agencies and hospices.
- End-stage renal disease facilities and dialysis centers.

Third, we will work with each State at both the regional and central office level. A Medicaid/State Children's Health Insurance Program contact person for each State will troubleshoot and resolve disputes for Governors, State Medicaid Directors, and other high-ranking State officials. The contact person will be directly accountable to the Administrator and the Director of the Center for Medicaid and State Operations as they respond to State issues.

Fourth, we will form in-house expert teams across program areas to develop new ways of conducting business that will reduce administrative burdens and simplify our policies and regulations. These teams will look to reduce administrative burden on providers, eliminate complexity when possible, augment some of the individual suggestions we hear in our listening forums, and make Medicare more ''user-friendly.'' These expert teams will be coordinated with the Secretary's Regulatory Reform Initiative and the Secretary's Advisory Committee on Regulatory Reform.

Fifth, providers have advised us that it has become increasingly more difficult for them to stay abreast of the many new and changing instructions concerning our programs. We wish to make it easier for them to understand and comply with our regulatory documents and program instructions and to provide more predictability to program changes. Therefore, we are proposing to issue quarterly provider updates that list provider-oriented regulations we plan to publish in the coming quarter, as well as the **Federal Register** publication date and page reference for all regulations published in the previous quarter. The full text of our regulations is available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is *http://www.access.gpo.gov/nara/index.html.*

The first update serves as a pilot. In the pilot phase of this project, we have established several business objectives that we are testing with this release of the provider update. First, this update will be sent to provider groups and associations for their assessment as to its usefulness of content and format. Second, because of the complexity of the policy decisions associated with much of our regulatory work, we are taking an intermediate step towards enhancing the consistency of our regulatory publications. Specifically, we intend, to the extent practical, to publish regulations on a predictable cycle once a month. We plan to publish CMS business in the **Federal Register** on the fourth Friday of each month. In fact, each issue of the provider update will identify the specific days. We will work in good faith to follow the substance and timing of the provider update in the majority of cases. However, because some of our regulatory work has statutory publication dates that fall outside the fourth Friday of the month, we will continue to comply with the statutory requirements. For example, the public comment period for one of our major payment proposed rules closed the beginning of October. To effectively address the number of comments we anticipate and the complexity of the issues, the final rule titled, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2002 (CMS–1169–FC),'' will be published on November 1, 2001.

In addition, there may be other instances when it is not possible to follow the schedule. We will work hard to minimize these situations to the greatest extent possible.

Also, the provider update will include all instructions (program memoranda, manual transmittals, and Operational Policy Letters) that affect health care providers. These provider-oriented Medicare instructions will be implemented at the beginning of the quarter following the quarter in which the provider update is published. We are proposing to published future provider updates on our Web site, *http://www.cms.gov,* the first business day of each calendar quarter to ensure wider access to this information. We also welcome comments relative to this approach.

In many instances, the publication of the quarterly provider update will lengthen the advance notification period we presently give providers; we will generally create a uniform 90-day period of notice before implementation of coverage and payment changes. We believe the predictability and uniformity offered by set publication and implementation timeframes would significantly reduce the burden on the provider community that our current ''flow basis'' publication processes impose. Further, we believe the benefits gained from predictable publication and implementation timeframes would significantly outweigh the disadvantages of the delays in coverage and payment changes that may occur.

Sixth, we are planning to enhance our system of provider training on new requirements and the resolution of problems through formal training, satellite broadcasts, and web-based information.

Finally, we are revamping the process for developing, reviewing, and clearing all correspondence and, in particular, congressional correspondence. Our goal is to substantially reduce our response time to congressional inquiries by December 1, 2001; thus, greatly improving our responsiveness to our constituency.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Statement

This notice does not require an impact analysis because it does not have an economic impact on small entities, small rural hospitals, or State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 7, 2001.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–27700 Filed 11–1–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF–PA–HS–02–01A]

Discretionary Announcement of the Availability of Funds and Request for Applications for Select Service Areas of Early Head Start; Correction

AGENCY: Administration for Children, Youth and Families, ACF, DHHS.

ACTION: Correction.

SUMMARY: This document contains a correction to the Notice that was published in the **Federal Register** on September 20, 2001.

On page 48475, Appendix A, Part II, in the State of Missouri, in the County of St. Charles, in the FY 2002 funding level column, delete ''1,470,549'' and add ''1,497,549''.

On page 48476, Appendix A, Part II, in the State of New York, in the County of Bronx, in the FY 2002 funding level column, delete ''1,334,471'' and add ''1,322,291''. In the State of New York, in the County of Cattaraugus, in the FY 2002 funding level column, delete ''468,962'' and add ''511,079''. In the State of New York, in the County of Cattaraugus, in the FY 2002 funding level column, delete ''450,808'' and add ''568,205''. In the State of New York, in the County of Chenango, in the FY 2002 funding level column, delete ''468,962'' and add ''511,079''. In the State of New York, in the County of Monroe, in the FY 2002 funding level column, delete ''1,995,614'' and add ''2,173,928''. In the State of New York, in the County of Rensselaer, in the FY 2002 funding level column, delete ''670,221'' and add ''732,234''. In the State of New York, in the County of Steuben, in the FY 2002 funding level column, delete ''329,700'' and add ''349,700''. In the State of New York, in the County of Westchester, in the FY 2002 funding level column, delete ''941,224'' and add ''1,033,799''. In the State of New York, in the County of Erie, in the FY 2002 funding level column, delete ''1,277,058'' and add ''1,381,901''. In the State of New York, in the County of Schenectady, in the FY 2002 funding level column, delete ''1,057,663'' and add ''743,672''.

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1–800–351–2293 or send an e-mail to *ehs@lcgnet.com*. You can also contact Sherri Ash, Early Head Start, Head Start Bureau at (202) 205–8562.

Dated: October 29, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–27610 Filed 11–1–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0336]

Schering Corp. et al.; Withdrawal of Approval of 51 New Drug Applications and 25 Abbreviated New Drug Applications; 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 August 16, 2001 (66 FR 43017). The document announced the withdrawal of approval of 51 new drug applications (NDAs) and 25 abbreviated new drug applications (ANDAs). The document inadvertently withdrew approval of NDA 17–255 for DTPA (chelate) Multidose (kit for the preparation of Tc-99m pentetate injection) held by Nycomed Amersham Imaging, 101 Carnegie Center, Princeton, NJ 08540. FDA confirms that approval of NDA 17–255 is still in effect.

EFFECTIVE DATE: August 16, 2001.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

In FR Doc. 01–20605 appearing on page 43017 in the **Federal Register** of Thursday, August 16, 2001, the following correction is made: On page 43018, in the table, the entry for NDA 17–255 is removed.

Dated: October 11, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–27520 Filed 11–01–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0494]

Prescription Drug Products; Doxycycline and Penicillin G Procaine Administration for Inhalational Anthrax (Post-Exposure)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is clarifying that the currently approved indications for doxycycline and penicillin G procaine drug products include use in cases of inhalational exposure to *Bacillus anthracis* (the bacterium that causes anthrax). We also are providing dosing regimens that we have determined are appropriate for these products for this use. We encourage the submission of supplemental new drug applications (labeling supplements) to add the dosage information to the labeling of currently marketed drug products.

ADDRESSES: Submit labeling supplements to the Center for Drug Evaluation and Research, Food and Drug Administration, Central Document Room, 12229 Wilkins Ave., Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dianne Murphy, Center for Drug Evaluation and Research (HFD–950),