proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 8, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2011–20495 Filed 8–11–11; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcement of a Single Source Grant Award to the Tribal Law and Policy Institute

AGENCY: Children's Bureau, Administration on Children, Youth and Families, HHS.

ACTION: Notice to award a single source program expansion supplement grant to the Tribal Law and Policy Institute, located in West Hollywood, CA, to support activities of the National Resource Center for Tribes under the Tribal Maternal, Infant, Early Childhood Home Visiting Program.

CFDA Number: 93.508.

Statutory Authority: Social Security Act, Title V, Section 511 (42 U.S.C. 701), as amended by the Patient Protection and Affordable Care Act of 2010 (ACA), Pub. L. 111–148.

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Children's Bureau (CB) announces the award of a single source program expansion supplement grant to the Tribal Law and Policy Institute, West Hollywood, CA, for the National Resource Center (NRC) for Tribes. The program expansion supplement funds will be used to provide technical assistance and support for the planning, development and implementation of the Tribal Maternal, Infant and Early Childhood Home Visiting program.

The NRC for Tribes will provide technical assistance to ACF Tribal Home Visiting grantees to enhance their capacity to plan for and implement high-quality, evidence-based, and evidence-informed programs. Implementation of the NRC4Tribes work will include engaging, assessing, informing and supporting culturally-appropriate Tribal home visiting services that are part of coordinated early childhood systems in the American Indian and Alaska Natives (AIAN) communities and that support quality and effectiveness of services for AIAN children, youth, and families, which leads to increased safety, permanency, and well-being for children.

The Tribal Law and Policy Institute NRC for Tribes and its partner agencies are uniquely qualified to provide training and technical assistance to Tribes based upon their experience, expertise, and commitment to increasing cultural competency and sensitivity to the Tribal point of view in training and technical assistance. The NRC for Tribes expertise in Tribal culture, child maltreatment prevention, collaboration, evaluation, and implementation of evidence-based programs and practices makes them an appropriate recipient of supplemental funds to carry out this project.

Amount of Award: $150,000.

Project Period: May 15, 2011 to September 30, 2011.

FOR FURTHER INFORMATION CONTACT: Roshanda Shoulders, Children's Bureau, 1250 Maryland Ave., SW., 8th Floor, Washington, DC 20024. Telephone: (202) 401–5323. E-mail: *roshanda.shoulders@acf.hhs.gov.*

Dated: August 2, 2011.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2011–20278 Filed 8–11–11; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0271]

Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments, including scientific and other information, concerning the harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke. This information will assist the Agency in establishing a list of HPHCs in tobacco products and tobacco smoke (the HPHC list).

DATES: Submit either electronic or written comments by October 11, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 904(e) of the FD&C Act (21 U.S.C. 387d(e)), as added by the Tobacco Control Act, requires FDA to establish, and periodically revise as appropriate, ''a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.'' Section 904(e) of the FD&C Act also requires that FDA ''publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.''

The Agency has solicited scientific and other information from interested persons and has developed a list of tobacco product constituents it currently believes are harmful or potentially harmful to health. Although the Agency's work to date reflects consideration of substantial scientific and other information, we believe that additional information from the public may be beneficial to the Agency before it establishes the list described in section 904(e) of the FD&C Act. We are therefore publishing the Agency's

current list as table 1 of this document and requesting public comment as described in section II of this document. In this section of the document, we are also providing information about the Agency's guidance on HPHCs, the criteria that the Agency used to help develop the list, and reasons the Agency might add or remove constituents.

On June 10, 2010, FDA announced the availability for public comment of a draft guidance for industry and FDA staff entitled ''Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act'' (75 FR 32952). FDA announced the availability of the final guidance on January 31, 2011 (76 FR 5387) (available at *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation*) (HPHC final guidance). This final guidance represents the Agency's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing section 904(e) of the FD&C Act. It states: ''FDA believes that the phrase 'harmful and potentially harmful constituent' includes any chemical or chemical compound in a tobacco product or in tobacco smoke: (a) That is or potentially is inhaled, ingested, or absorbed into the body; and (b) that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products.''(HPHC final guidance at page 2). The HPHC final guidance includes examples of constituents that have the potential to cause direct harm and examples of constituents that have the potential to cause indirect harm: ''Examples of constituents that have the 'potential to cause direct harm' to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds. Examples of constituents that have the 'potential to cause indirect harm' to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by: (1) Potentially facilitating initiation of the use of tobacco products; (2) potentially impeding cessation of the use of tobacco products; or (3) potentially increasing the intensity of tobacco product use (*e.g.,* frequency of use, amount consumed, depth of inhalation). Another example of a constituent that has the 'potential to cause indirect harm' is a constituent that may enhance the harmful effects of a tobacco product constituent.'' (HPHC final guidance at page 2).

On May 1, 2010, the Agency established a subcommittee of the Tobacco Products Scientific Advisory Committee (TPSAC),[1] the Tobacco Product Constituents Subcommittee (the subcommittee), and charged the subcommittee with making preliminary recommendations to TPSAC on HPHCs in tobacco products and tobacco smoke. The subcommittee held public meetings on June 8 and 9, 2010, and July 7, 2010. Prior to these meetings, FDA solicited data, information, and/or views on HPHCs in tobacco products and tobacco smoke from the public, and at the June meeting, presentations were made by interested persons.[2] At these meetings the subcommittee:

- Reviewed example lists of HPHCs developed by other countries and organizations;
- Identified criteria for selecting carcinogens, toxicants, and addictive chemicals or chemical compounds in tobacco products and tobacco smoke;
- Identified chemicals or chemical compounds that met the identified criteria;
- Confirmed the existence of methods for measuring each chemical or chemical compound identified; and
- Identified other potentially important information or criteria for measuring HPHCs in tobacco products or tobacco smoke, such as smoking machine regimens to be used in measuring HPHCs.

The subcommittee made preliminary recommendations to TPSAC.

On August 30, 2010, TPSAC held a public meeting to deliberate on the recommendations from the subcommittee. Prior to this meeting, FDA published a notice in the **Federal Register** soliciting data, information, and/or views from the public on the issues to be discussed at this meeting.[3] FDA asked what criteria TPSAC recommended the Agency use for determining whether a constituent is a carcinogen, toxicant, or addictive chemical or chemical compound that should be included on the HPHC list. As a result of its discussions, TPSAC recommended to the Agency the following criteria for selecting the HPHC list:

- Constituents identified as known, likely, probably, or possible human carcinogens by the U.S. Environmental Protection Agency (EPA);
- Constituents identified as known, probable, or possible carcinogens by the International Agency for Research on Cancer (IARC) including IARC Group 1 (carcinogenic to humans), IARC Group 2 (probably carcinogenic to humans), and IARC Group 2B (possibly carcinogenic to humans);
- Constituents identified as human carcinogens or reasonably anticipated to be human carcinogens by the National Toxicology Program (NTP);
- Constituents identified as potential occupational carcinogens by the National Institute for Occupational Safety and Health (NIOSH):
- Constituents identified by EPA or the Agency for Toxic Substances and Disease Registry (ATSDR) as having adverse respiratory or cardiac effects;
- Constituents identified by the California Environmental Protection Agency (CA EPA) as reproductive or developmental toxicants;
- Constituents having, based upon a review of the peer-reviewed literature, evidence of at least two of the following measures of abuse liability (addiction):
  - Central nervous system activity;
  - Animal drug discrimination;
  - Conditioned place preference;
  - Animal self-administration;
  - Human self-administration;
  - Drug liking;
  - Signs of withdrawal; and
- Constituents banned in food (for smokeless tobacco products).

FDA believes having criteria for use in determining whether a constituent is harmful or potentially harmful will be beneficial. FDA carefully evaluated the data, information, and views on HPHCs in tobacco products provided by TPSAC and the public, in light of the Agency's own knowledge and expertise, and taking into consideration its HPHC final guidance. Based on this evaluation, FDA tentatively concludes that it should use the criteria listed previously in this document in determining whether a constituent should be included on the HPHC list. Specifically, FDA has tentatively concluded that it should consider a constituent meeting these criteria to be harmful or potentially harmful, such that it should be included on the HPHC list, unless other scientific information obtained by or submitted to the Agency shows that the constituent is

[1] Information about TPSAC as well as information and background materials on TPSAC meetings are available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/default.htm.*

[2] See 75 FR 22147 (April 27, 2010), and 75 FR 33814 (June 15, 2010). Information submitted to the public docket for each of these meetings is available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm222977.htm* and *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm222978.htm.*

[3] See 75 FR 47308 (August 5, 2010). Information submitted by the public to the docket for this meeting is available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm232799.htm.*

not, in fact, harmful or potentially harmful. Applying this approach to the criteria and the available information, FDA developed table 1 of this document.

FDA recognizes that table 1 of this document may not include all constituents that are ''harmful or potentially harmful.'' For example, the criteria described previously in this document generally depend on a chemical or chemical compound being both studied and listed by another entity, such as constituents identified by EPA or ATSDR as having adverse respiratory or cardiac effects. The fact that a constituent has not been so identified by EPA or ATSDR could be because it has not been adequately studied or has not yet been systematically reviewed by relevant agencies, rather than because the constituent does not have adverse respiratory or cardiac effects. Moreover, FDA has only focused on the five disease outcomes of cancer, cardiovascular disease, respiratory effects, developmental or reproductive effects, and addiction. FDA intends to review other disease outcomes to assess whether additional chemicals or chemical compounds in tobacco products or tobacco smoke are harmful or potentially harmful constituents that contribute to the risk of other diseases. Similarly, the criteria FDA has tentatively selected are limited to those that relate to carcinogens, toxicants, and addictive chemicals or chemical compounds in tobacco products and tobacco smoke. We intend to consider whether additional criteria should be selected to help identify other classes of harmful or potentially harmful chemicals and chemical compounds for inclusion on the HPHC list, and whether individual constituents should be added. Just as these types of new information may lead to additions to the list, FDA recognizes that it may become aware of new scientific information about constituents of tobacco products that make it appropriate to remove one or more of the constituents that appear on the list. For these reasons, FDA will continue to review scientific information about tobacco product constituents. FDA intends to do this both before and after it establishes its list of HPHCs for the purpose of section 904(e) of the FD&C Act, consistent with the directive in section 904(e) that the Agency periodically revise the list as appropriate.

II. Request for Comments and Information

FDA is soliciting public comment, including scientific and other information, concerning the HPHCs in tobacco products and tobacco smoke. We are particularly interested in comments from the public on the following topics:

- The criteria FDA should use in determining whether a constituent is harmful or potentially harmful such that it should be included on the HPHC list;
- Whether any chemicals or chemical compounds not listed in table 1 of this document should be added because they are harmful or potentially harmful, including supporting scientific or other information; and/or
- Whether any of the chemicals or chemical compounds listed in table 1 of this document should be removed because they are not harmful or potentially harmful, including supporting scientific or other information.

III. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

TABLE 1—LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD)
Acetaldehyde	CA, RT, AD
Acetamide	CA
Acetone	RT
Acrolein	RT, CT
Acrylamide	CA
Acrylonitrile	CA, RT
Aflatoxin B1	CA
4–Aminobiphenyl	CA
1–Aminonaphthalene	CA
2–Aminonaphthalene	CA
Ammonia	RT
Anabasine	AD
o-Anisidine	CA
Arsenic	CA, CT, RDT
A-α-C (2-Amino-9*H*-pyrido[2,3-*b*]indole)	CA
Benz[*a*]anthracene	CA, CT
Benz[*j*]aceanthrylene	CA
Benzene	CA, CT, RDT
Benzo[*b*]fluoranthene	CA, CT
Benzo[*k*]fluoranthene	CA, CT
Benzo[*b*]furan	CA
Benzo[*a*]pyrene	CA
Benzo[*c*]phenanthrene	CA
Beryllium	CA
1,3–Butadiene	CA, RT, RDT
Cadmium	CA, RT, RDT

TABLE 1—LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD)
Caffeic acid	CA
Carbon monoxide	RDT
Catechol	CA
Chlorinated dioxins/furans	CA, RDT
Chromium	CA, RT, RDT
Chrysene	CA, CT
Cobalt	CA, CT
Coumarin	Banned in food
Cresols (o-, m-, and p-cresol)	CA, RT
Crotonaldehyde	CA
Cyclopenta[*c,d*]pyrene	CA
Dibenz[*a,h*]acridine	CA, CT
Dibenz[*a,j*]acridine	CA
Dibenz[*a,h*]anthracene	CA
Dibenzo[*c,g*]carbazole	CA
Dibenzo[*a,e*]pyrene	CA
Dibenzo[*a,h*]pyrene	CA
Dibenzo[*a,i*]pyrene	CA
Dibenzo[*a,l*]pyrene	CA
2,6-Dimethylaniline	CA
Ethyl carbamate (urethane)	CA, RDT
Ethylbenzene	CA
Ethylene oxide	CA, RT, RDT
Formaldehyde	CA, RT
Furan	CA
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-*a*:3',2'-*d*]imidazole)	CA
Glu-P-2 (2-Aminodipyrido[1,2-*a*:3',2'-*d*]imidazole)	CA
Hydrazine	CA, RT
Hydrogen cyanide	RT, CT
Indeno[*1,2,3-cd*]pyrene	CA
IQ (2-Amino-3-methylimidazo[4,5-*f*]quinoline)	CA
Isoprene	CA
Lead	CA, CT, RDT
MeA-α-C (2-Amino-3-methyl)-9*H*-pyrido[2,3-*b*]indole)	CA
Mercury	CA, RDT
Methyl ethyl ketone	RT
5-Methylchrysene	CA
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	CA
Naphthalene	CA, RT
Nickel	CA, RT
Nicotine	RDT, AD
Nitrobenzene	CA, RT, RDT
Nitromethane	CA
2-Nitropropane	CA
N-Nitrosodiethanolamine (NDELA)	CA
N-Nitrosodiethylamine	CA
N-Nitrosodimethylamine (NDMA)	CA
N-Nitrosomethylethylamine	CA
N-Nitrosomorpholine (NMOR)	CA
N-Nitrosonornicotine (NNN)	CA
N-Nitrosopiperidine (NPIP)	CA
N-Nitrosopyrrolidine (NPYR)	CA
N-Nitrososarcosine (NSAR)	CA
Nornicotine	AD
Phenol	RT, CT
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine)	CA
Polonium-210	CA
Propionaldehyde	RT, CT
Propylene oxide	CA, RT
Quinoline	CA
Selenium	RT
Styrene	CA
o-Toluidine	CA
Toluene	RT, RDT
Trp-P-1 (3-Amino-1,4-dimethyl-5*H*-pyrido[4,3-*b*]indole)	CA
Trp-P-2 (1-Methyl-3-amino-5*H*-pyrido[4,3-*b*]indole)	CA

TABLE 1—LIST OF THE CHEMICALS AND CHEMICAL COMPOUNDS IDENTIFIED BY FDA AS HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE—Continued

Constituent	Carcinogen (CA), respiratory toxicant (RT), cardiovascular toxicant (CT), reproductive or developmental toxicant (RDT), addictive (AD)
Uranium-235	CA, RT
Uranium-238	CA, RT
Vinyl acetate	CA, RT
Vinyl chloride	CA

Dated: August 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20502 Filed 8–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0556]

Center for Devices and Radiological Health 510(k) Clearance Process; Recommendations Proposed in Institute of Medicine Report: ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years;'' Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled: ''Recommendations Proposed in Institute of Medicine Report: 'Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years.' '' The purpose of the public meeting is to encourage public comment on the recommendations proposed in the Institute of Medicine (IOM) report.

Date and Time: The public meeting will be held on September 16, 2011, from 8:30 a.m. to 5 p.m. Submit electronic and written comments by September 30, 2011.

Location: The public meeting will be held at the Silver Spring Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993, 301–796–5678, *philip.desjardins@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this meeting must register online by 5 p.m. on September 15, 2011. For those without Internet access, please call the contact person to register.

Early registration is recommended because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (email: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than September 15, 2011.

To register for the public meeting, please visit *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public meeting from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone, and FAX number. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

This meeting includes a public comment session. During online registration you may indicate if you wish to make an oral presentation during a public comment session at the public meeting, and which topic you wish to address in your presentation. FDA has included topics for comment in this document. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. All requests to make oral presentations, as well as presentation materials, must be sent to the contact person by September 15, 2011.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments until September 30, 2011. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. What is the background and purpose for holding this public meeting?

In September 2009, FDA's Center for Devices and Radiological Health (CDRH) convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the premarket notification (510(k)) process. The first prong of this evaluation consisted of an internal evaluation of the 510(k) process, resulting in the publication of the CDRH preliminary internal evaluation entitled ''510(k) Working Group Preliminary Report and Recommendations'' (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf*). This preliminary report was intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. The report was issued on August 5, 2010 (75 FR 47307). After reviewing public comment, CDRH issued a plan of action for implementation of the previously announced