

synergistic herbs (+ calcium in the tablets).” Cleansing Time Pro Black Salve is an ointment that respondent recommends for external use. Alternatively, respondent recommends that consumers take the product internally by purchasing Black Salve Tablets or by placing an amount of the Black Salve ointment into a gelatin capsule.

The Commission’s complaint charges that respondent claimed that Cleansing Time Pro Black Salve & Tablets were effective to treat, prevent, or cure numerous forms of cancer and various viral infections, including hepatitis, HIV, SARS, West Nile Virus, and Avian Bird Flu. The complaint alleges that respondent did not have a reasonable basis for these claims. The Commission’s complaint also challenges respondent’s testimonial advertising. The complaint alleges that respondent failed to disclose adequately that one of the endorsers was respondent Holly A. Bacon herself. The complaint alleges that this was a deceptive act or practice, because the fact that one of the endorsers had a material connection with Cleansing Time Pro would materially affect the weight and credibility given by consumers to the endorsement and would be material to consumers in their purchase or use of the products.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I requires respondent to have competent and reliable scientific evidence substantiating any claim that Cleansing Time Pro Black Salve & Tablets, or any other covered product or service, is effective in the prevention, treatment or cure of cancer, cancer, hepatitis, HIV, SARS, West Nile Virus, or Avian Bird Flu. A “covered product or service” is defined as any food, dietary supplement, or drug, including, but not limited to, Cleansing Time Pro Black Salve & Tablets, or any other health-related product, service, or program. Part II requires that any future claim about the absolute or comparative benefits, performance, efficacy, safety or side effects of any covered product or service be truthful and supported by competent and reliable scientific evidence.

Part III of the proposed order addresses the deceptive endorsement claim by requiring that respondent disclose any material connection between an endorser and respondent, if such a connection exists. “Material connection” is defined as any relationship that materially affects the weight or credibility of the user

testimonial or endorsement and that would not reasonably be expected by consumers.

Part IV of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative or final Food and Drug Administration (“FDA”) standard or under any new drug application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires respondent to compile a list of all consumers who purchased Cleansing Time Pro Black Salve & Tablets from respondent since July 1, 2005, and to mail a letter (Attached to the proposed order as Attachment A) to each purchaser describing the scientific evidence related to these products. Part VI prohibits respondent from providing any identifying information about her purchasers to anyone other than the Commission, another law enforcement agency, or as required by law.

Parts VII through X of the proposed order require respondent to keep copies of relevant advertisements and materials that substantiate claims made in the advertisements; to provide copies of the order to certain of her employees; to notify the Commission of her affiliation with any new health-related business or employment; and to file compliance reports with the Commission. Part XI of the proposed order is a “sunset” provision, dictating that the order will terminate twenty years from the date it is issued or twenty years after a complaint is filed in federal court, by either the United States or the FTC, alleging any violation of the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E8-23327 Filed 10-2-08; 8:45 am]

BILLING CODE 6750-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices, (ACIP)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 8 a.m.–6 p.m., October 22, 2008; 8 a.m.–5 p.m., October 23, 2008.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent “Oz” Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The agenda will include discussions on Pneumococcal Vaccines; Anthrax Vaccine; General Recommendations; Human Papillomavirus Vaccines; Adult Immunization Schedules; 2009 Immunization Schedules for children 0–18 years of age; Hepatitis Vaccines; Japanese Encephalitis Vaccine; Rabies Vaccine Supply; Influenza; Immunization Safety Update; Vaccine Supply; Adolescent National Immunization Survey Results; Rotavirus Vaccines; MMRV Vaccine; and Tdap (Boostrix) in Adults.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Antonette Hill, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., Mailstop (E-05), Atlanta, Georgia 30333, Telephone (404)639-8836, Fax (404)639-8905.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee

management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 25, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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BILLING CODE 4160-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Granting of a Co-Exclusive License

AGENCY: Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), is contemplating the granting of a co-exclusive worldwide license to practice the invention embodied in the patent application referred below to Mk-IX Technologies, having a place of business in Huntsville, Alabama. CDC intends to grant rights to practice this invention to no more than one other co-licensee. The patent rights in these inventions have been assigned to the government of the United States of America. The patent application to be licensed is:

Non-Provisional Patent Application

Title: Wipes and Methods for Removal of Metal Contamination from Surfaces.

Serial No. 11/039,178.

Filing date: 01/18/2005.

Issue Date: Patent pending.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, telephone: (770) 488-8610; facsimile: (770) 488-8615. Applications for an exclusive license filed in response to this notice will be

treated as objections to the grant of the contemplated co-exclusive license. Only written comments and/or applications for a license which are received by CDC within thirty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: September 26, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E8-23398 Filed 10-2-08; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10001, CMS-10009, CMS-10272 and CMS-10242]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) 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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Portability and Accountability Act (HIPAA) Nondiscrimination Provisions and Supporting Regulations in 45 CFR 146.121(h) and 121(i)(2)(i); *Use:* If

coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan had exempt the plan from the nondiscrimination requirements under 45 CFR 146.180 "Treatment of Non-Federal Governmental Plans", and the plan sponsor subsequently chooses to bring the plan into compliance, the plan sponsor must comply with the requirements under 45 CFR 146.121(i)(2)(i) "Special Transitional Rule for Self-Funded Non-Federal Governmental Plans Exempted under 45 CFR 146.180". To bring the plan into compliance with the requirements, the plan must notify the individual that the plan will be coming into compliance, afford the individual an opportunity to enroll, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance. *Form Number:* CMS-10001 (OMB# 0938-0827); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 194.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Portability and Accountability Act (HIPAA) Nondiscrimination Provisions and Supporting Regulations in 45 CFR 146.121(f)(2)(v)(A); *Use:* Section 146.121 of the regulations requires Health plans or issuers to disclose in all plan materials the terms of certain wellness programs including the availability of a reasonable alternative standard. Plan participants and their dependents need this information to understand the rights they have under HIPAA. States and the Federal government may need the information supplied by issuers to properly perform their regulatory functions. *Form Number:* CMS-10009 (OMB# 0938-0819); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 2,600; *Total Annual Responses:* 2,600; *Total Annual Hours:* 1,300.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Hospital Leadership Quality Assessment Tool (HLQAT); *Use:* In 2006, the Hospital Leadership Collaborative (HLC) launched a public-private partnership to develop a CMS-endorsed self-assessment tool, "The Hospital Leadership and Quality Assessment Tool" (HLQAT) to assist hospitals in the improvement of quality through enhanced hospital governance,