

collection of oral health data from 1,000 middle- and high-school students in Colorado communities with naturally occurring fluoride in the tap water at or exceeding one part per million. CDC is funding the Colorado State Health Department to implement the collection by recruiting eligible schools and dental examiners, gaining consent, arranging logistics, and collecting de-identified examination data and photos taken by the dental examiners. CDC is funding a national expert in dental public health data collection to train the examiners. Finally, CDC is funding researchers at Purdue University to develop photo-taking protocols and deep learning algorithms to identify dental conditions. Data collected for each student will include: (1) human assessment of fluorosis severity in the six upper anterior teeth, and caries/sealant

assessment of the occlusal surfaces of the eight permanent molars; and (2) nine smartphone digital photos of the upper anterior teeth and 24 intraoral camera digital photos of the occlusal surfaces of the eight permanent molars. Digital photos of the teeth and the completed paper screening form will be uploaded to a HIPAA compliant cloud storage box that can only be accessed by examiners and designated CDC researchers with administrative rights. CDC is authorized to collect this information under the Public Health Service Act, title 42, section 247b-14, Oral health promotion and disease prevention; and the Public Health Service Act, title 42, section 301.

CDC proposes using data collected from 750 students to train the deep learning algorithms to assess caries, sealants, and fluorosis and data from

250 students to evaluate the accuracy of the algorithms in terms of agreement with standardized examiner assessment. Manuscripts on: (1) the methodologies used to ensure sufficient photo quality when taken under field conditions; and (2) the performance of the deep learning algorithms will be submitted to peer-reviewed journals. The deep learning tool, if sufficiently accurate, will be piloted in one data collection cycle of NHANES that is administered by the National Centers for Health Statistics (NCHS). Ultimately, the tool would be shared with the State and local oral health programs and other pertinent partners.

CDC requests OMB clearance for data collection for one year. The total estimated annualized burden hours are 827. There are no costs to student respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Child	Screening/photo/form	1,000	1	16/60
Parent or caretaker	Consent	1,000	1	1/60
Screener	Screening/photo form includes training, travel, screening and photos, and ongoing technical assistance.	6	1	90/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health; Notice of Charter Renewal

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

ACTION: Notice of charter renewal.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the renewal of the charter of the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

FOR FURTHER INFORMATION CONTACT:

Maria Strickland, M.P.H., Designated Federal Officer, Board of Scientific Counselors, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, 400 7th Street SW, Suite 5W, Constitution Center, Washington, District of Columbia 20024. Telephone: (202) 245-0649; Email: MStrickland2@cdc.gov.

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001-1014. This charter has been renewed for a two-year period through February 3, 2025.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0643]

Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Labeling for Biosimilar and Interchangeable Biosimilar Products." This draft guidance is intended to help applicants develop draft labeling for proposed