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SUPPLEMENTARY INFORMATION:

I. Background

This document is related to two documents published elsewhere in this issue of the **Federal Register**, wherein FDA is announcing: (1) The availability of a draft guidance entitled “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209” (draft GFI #213); and (2) the availability of a draft proposed regulation for veterinary feed directives.

In the **Federal Register** of June 29, 2010 (75 FR 37450), FDA published the notice of availability for a draft guidance entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” giving interested persons until August 30, 2010, to comment on the draft guidance. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. Minor editorial changes were made to improve clarity.

The Agency was pleased to receive a number of comments that were generally supportive of the concepts outlined in draft GFI #209. However, other comments were more critical, based largely on the guidance’s lack of specificity related to implementation issues. FDA decided not to make any substantive changes to GFI #209 but rather to address specific issues related to implementation through issuance of a separate draft guidance document, draft GFI #213, that would afford additional opportunity for public comment. As noted earlier, a notice of availability for draft GFI #213 is published elsewhere in this issue of the **Federal Register**.

The guidance announced in this notice finalizes the draft guidance dated June 28, 2010.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind

FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

IV. 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. 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.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: April 5, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of Corps Personnel Obligated Under the National Health Service Corps Scholarship Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National Health Service Corps (NHSC) scholarship recipients (Corps Personnel, Corps members) during the period July 1, 2012, through June 30, 2013, is posted on the NHSC Web site at <http://datawarehouse.hrsa.gov/HGDWRReports/OneClickRptFilter.aspx?rptName=NHSCAppSiteList&rptFormat=HTML3.2>. This searchable database specifies all

currently approved NHSC service sites, by State, and can be utilized to determine which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program based on the threshold HPSA score set forth below. Please note that entities on this list may or may not have current job opportunities for NHSC scholars. Furthermore, not all vacancies associated with sites on the list described below will be for Corps members, but could be for NHSC Scholarship Program participants serving their obligation through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA designation by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP); (3) enter into an agreement with the State agency that administers Medicaid and CHIP, accept assignment under Medicare, see all patients regardless of their ability to pay and post such policy, and use and post a discounted fee plan; and (4) be determined by the Secretary to have: (a) A need and demand for health manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development, and training opportunities for Corps members.

Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a

Corps member is not assigned to the entity. Sites that provide specialized care, or a limited set of services may not receive approval as NHSC service sites. This may include clinics that focus on one disease or disorder or offer limited services, such as a clinic that only provides immunizations or a substance abuse clinic.

Entities that receive assignment of Corps personnel must assure that: (1) The position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in the requisite amount of clinical practice, as defined below, to meet his or her service obligation:

Full-Time Clinical Practice

“Full-time clinical practice” is defined as a minimum of 40 hours per week for at least 45 weeks per service year. The 40 hours per week may be compressed into no less than 4 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the full-time service obligation, except to the extent the provider is directly treating patients during that period.

For all health professionals, except as noted below, at least 32 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s) during normally scheduled office hours. The remaining 8 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching activities at the approved service site shall not exceed 8 hours of the minimum 40 hours per week, unless the teaching takes place in a HRSA-funded Teaching Health Center (see Sec. 340H of the U.S. Public Health Service Act, 42 United States Code Sec. 256h). Teaching activities in a HRSA-funded Teaching Health Center shall not exceed 20 hours of the minimum 40 hours per week.

For obstetrician/gynecologists, certified nurse midwives (CNMs), family medicine physicians who practice obstetrics on a regular basis, providers of geriatric services, pediatric dentists, and behavioral/mental health providers, at least 21 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 19 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. No more than 8 hours per week can be spent performing practice-related administrative activities.

Teaching activities at the approved service site shall not exceed 8 hours of the minimum 40 hours per week, unless the teaching takes place in a HRSA-funded Teaching Health Center. Teaching activities in a HRSA-funded Teaching Health Center shall not exceed 20 hours of the minimum 40 hours per week.

For physicians (including psychiatrists), physician assistants, nurse practitioners (including those specializing in psychiatry or mental health), and certified nurse midwives serving in a Critical Access Hospital (CAH)—defined as a nonprofit facility that is: (a) Located in a State that has established with the Centers for Medicare and Medicaid Services (CMS) a Medicare rural hospital flexibility program; (b) designated by the State as a CAH; (c) certified by the CMS as a CAH; and (d) in compliance with all applicable CAH conditions of participation—at least 16 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the CAH-affiliated outpatient ambulatory care setting(s) specified in the NHSC’s Customer Service Portal, during normally scheduled office hours. The remaining 24 hours of the minimum 40 hours per week must be spent providing direct patient care for patients or teaching at the CAH(s) or the CAH-affiliated outpatient ambulatory care setting specified in the Customer Service Portal, providing direct patient care in the CAH’s skilled nursing facility or swing bed unit, or performing practice-related administrative activities. No more than 8 hours per week can be spent on practice-related administrative activities. Teaching activities at the approved service site(s) shall not exceed 8 hours of the minimum 40 hours per week, unless the teaching takes place in a HRSA-funded Teaching Health Center (THC) (see Sec. 340H of the U.S. Public Health Service Act, 42 United States Code Sec. 256h). Teaching activities in a HRSA-funded THC shall not exceed 20 hours of the minimum 40 hours per week.

Half-Time Clinical Practice

“Half-time clinical practice” is defined as a minimum of 20 hours per week (not to exceed 39 hours per week), for at least 45 weeks per service year. The 20 hours per week may be compressed into no less than 2 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the half-time service obligation, except to the extent the provider is directly serving patients during that period.

For all health professionals, except as noted below, at least 16 of the minimum 20 hours per week must be spent providing direct patient care in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 4 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching and practice-related administrative activities shall not exceed a total of 4 hours of the minimum 20 hours per week.

For obstetrician/gynecologists, certified nurse midwives (CNMs), family medicine physicians who practice obstetrics on a regular basis, providers of geriatric services, pediatric dentists, and behavioral/mental health providers, at least 11 of the minimum 20 hours per week must be spent providing direct patient care in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s), during normally scheduled office hours. The remaining 9 hours per week must be spent providing clinical services for patients or teaching in the approved practice site(s), providing clinical services in alternative settings as directed by the approved practice site(s), or performing practice-related administrative activities. Teaching and practice-related administrative activities shall not exceed 4 hours of the minimum 20 hours per week.

For physicians (including psychiatrists), physician assistants, nurse practitioners (including those specializing in psychiatry or mental health), and certified nurse midwives serving in a Critical Access Hospital (CAH), at least 8 of the minimum 20 hours per week must be spent providing direct patient care or teaching in the CAH-affiliated outpatient ambulatory care setting(s) specified in the Customer Service Portal, during normally scheduled office hours. The remaining 12 hours of the minimum 20 hours per week must be spent providing direct patient care for patients or teaching at the CAH(s) or the CAH-affiliated outpatient ambulatory care setting specified in the Practice Agreement, providing direct patient care in the CAH’s skilled nursing facility or swing bed unit, or performing practice-related administrative activities. Teaching and practice-related administrative activities shall not exceed 4 hours of the minimum 20 hours per week.

Half-time clinical service is not an option for scholars serving their obligation through the Private Practice Option.

In addition to utilizing NHSC assignees in accordance with their full-time or half-time service obligation (as defined above), sites receiving assignment of Corps personnel are expected to: (1) Report to the NHSC all absences, including those in excess of the authorized number of days (up to 35 full-time days per service year in the case of full-time service and up to 35 half-time days per service year in the case of half-time service); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents for NHSC assignees (including documentation, if applicable, of the reason(s) for the termination of an NHSC clinician’s employment at the site prior to his or her obligated service end date); and (4) submit an NHSC Site Survey, or a Uniform Data System (UDS) report in the case of entities receiving HRSA grant support under Sec. 330 of the Public Health Service Act. The Site Survey or UDS report, as applicable, require the site to assess the age, sex, race/ethnicity of, and provider encounter records for its user population and are site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in the survey includes all activity at the

site(s) to which the Corps member is assigned.

Evaluation and Selection Process

In order for a site to be eligible for placement of NHSC personnel, it must be approved by the NHSC following the site's submission of a Site Application. The processing of Site Applications from solo or group practices may involve additional screening, including a site visit by NHSC representatives. The Site Application approval is good for a period of 3 years from the date of approval.

In approving applications for the assignment of Corps members, the Secretary shall give priority to any such application that is made regarding the provision of primary health services to a HPSA with the greatest shortage. For the program year July 1, 2012, through

June 30, 2013, HPSAs of greatest shortage for determination of priority for assignment of NHSC scholarship-obligated Corps personnel will be defined as follows: (1) Primary medical care HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are primary care physicians, family nurse practitioners (NPs), physician assistants (PAs) or CNMs; (2) mental health HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are psychiatrists or mental health nurse practitioners; and (3) dental HPSAs with scores of 16 and above are authorized for the assignment of NHSC scholarship recipients who are dentists. The NHSC has determined that a minimum HPSA score of 16 for all eligible clinicians will enable it to meet its statutory obligation to identify a number of entities eligible for placement at least equal to, but not greater than, twice the number of NHSC scholars available to serve in the 2012–2013 placement cycle.

The number of new NHSC placements through the Scholarship Program allowed at any one site is limited to one (1) of the following provider types: Physician (MD/DO), NP, PA, CNM, or dentist. The NHSC will consider requests for up to two (2) scholar placements at any one site on a case-by-case basis. Factors that are taken into consideration include community need, as measured by demand for services, patient outcomes and other similar factors, and how the additional scholar will impact retention of other clinicians. Sites wishing to request an additional scholar must complete an Additional Scholar Request form available at <http://nhsc.hrsa.gov/scholarship/pdf/additionalscholarrequestform.pdf>.

Sites that do not meet the authorized HPSA score threshold indicated above may post job openings, however, scholars seeking placement between July 1, 2012 and June 30, 2013 will be advised that they can only compete for open positions at sites that meet the threshold placement HPSA score of 16. While not eligible for scholar placements in 2012–2013, vacancies in HPSAs scoring less than 16 will be used by the NHSC in evaluating the HPSA threshold score for the next scholarship placement cycle.

Application Requests, Dates and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of Corps personnel may be updated periodically. Entities that no longer meet eligibility criteria, including those sites whose 3-year approval as an NHSC service site has lapsed or whose HPSA designation has been withdrawn or proposed for withdrawal, will be removed from the priority listing. New entities interested in being added to the high priority list must submit a Site Application to the National Health Service Corps by visiting <http://nhsc.hrsa.gov/communities/apply.htm> to apply online. A searchable database of HPSAs and their scores, by State and county, is posted at <http://hpsafind.hrsa.gov/>.

Additional Information

Entities wishing to provide additional data and information in support of their inclusion on the proposed list of HPSAs and entities that would receive priority in assignment of scholarship-obligated Corps members, must do so in writing no later than May 14, 2012. This information should be submitted to: Sonya Bayone, Chief, Site Branch, Division of the National Health Service Corps, Bureau of Clinician Recruitment and Service, 5600 Fishers Lane, Room 8–37, Rockville, MD 20857. This information will be considered in preparing the final list of HPSAs and entities that are receiving priority for the assignment of scholarship-obligated Corps personnel.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR Part 100).

Dated: April 9, 2012.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Solar Cell: A Mobile UV Manager for Smart Phones Phase II (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 27, 2012 (77 FR 4334) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Solar Cell: A Mobile UV Manager for Smart Phones Phase II (NCI). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The overall goal of the study is to design a smart phone application, *Solar Cell*, which uses smart phone technology to aid users in protecting their skin from damaging ultraviolet radiation (UV) in sunlight, a primary cause of skin cancer. The purpose of this part of the study is to produce, deploy, and evaluate the effectiveness of a state-of-the-art software application for smart phones (i.e., mobile application), “*Solar Cell*.” This software application supports decision-making related to sun protection and exposure by Americans to reduce the risk of developing skin cancer attributable to chronic and severe UV exposure and developing other cancers attributable to vitamin D deficiency. The *Solar Cell* mobile smart phone application combines personal and behavior data with geo-spatial data (i.e., UV Index forecast, time, and location) and delivers actionable sun protection advice to reduce risk of skin cancer. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adults (18 and over) from the U.S. population who own Android smart phones. The annual reporting burden is estimated at 308 hours (see Table below). There are no Capital