TABLE A.2—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1—Continued
[July 2010 to December 2010]

Recruitment strategy	Activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
	Pregnancy Probability Group Follow Up Script.	Age-Eligible Women.	761	6	0.1	456
	Pregnancy Activities					
	Women's Informed Consent Form.	Pregnant Women ..	9,504	1	0.67	6,368
	Pregnancy Visit 1 Interview	Pregnant Women ..	3,552	1	1	3,552
	Pregnancy Visit 2 Interview	Pregnant Women ..	3,552	1	0.75	2,664
	Birth-Related Activities					
	Birth Visit Interview	Mother/Baby	1,857	1	0.4	743
	Total—Stage 1	.....	35,826	.....	.....	21,006
Grand Total, Recruitment Substudy		.....	334,308	.....	.....	128,039

The estimated annualized cost to respondents is $1,782,053 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, *Attention:* Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jamelle E. Banks, M.P.H., National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 443–7210, or e-mail your request, including your address to *banksj@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 15, 2010.

Jamelle E. Banks,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–14969 Filed 6–18–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0002]

Notice of Approval of a Supplemental New Animal Drug Application; Penicillin G Procaine Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Norbrook Laboratories, Ltd. The supplemental NADA provides for a revised formulation of penicillin G procaine injectable suspension that includes lecithin as a surfactant.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed a supplement to NADA 065–010 for use of NOROCILLIN (penicillin G procaine) Injectable Suspension by intramuscular injection in cattle, sheep, swine, and horses. The supplement provides for a revised formulation that includes lecithin as a surfactant. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and part 514 (21 CFR 514), in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of April 23, 2010.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 15, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–14865 Filed 6–18–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0277]

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of seven Emergency Use Authorizations (EUAs) (the Authorizations), two of which were amended after initial issuance, for certain in vitro diagnostic devices. FDA is issuing the Authorizations and amendments thereto under the Federal Food, Drug, and Cosmetic Act (the act). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow the determination by the then Acting Secretary of the U.S. Department of Health and Human Services Charles E. Johnson (the Acting Secretary) that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorizations, which include explanations of the reasons for their issuance or reissuance, are reprinted in this document.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for effective dates of the Authorizations.

ADDRESSES: Submit written requests for single copies of the Emergency Use Authorization(s) to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4140, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4140, Silver Spring, MD 20993, 301–796–8510.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. § 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds:

(1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) A determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) A determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e, respectively) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and the Center for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency), FDA[1] concludes:

(1) that an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that:

(A) the product may be effective in diagnosing, treating, or preventing—

(1) such disease or condition; or

(2) a serious or life-threatening disease or condition caused by a product authorized under section 564 of the act, approved or cleared under the act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and

[1] The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.