preventing or treating viral infections are claimed in the patents issued for this invention.

Applications:

- Prophylactic and/or therapeutic treatment for HIV infection.
- Topical microbicide treatment to protect against HIV infection.
- Imaging of HIV infected cells in tissues.

Advantages:

- High neutralization efficiency due to unique bifunctional binding characteristics.
- Potentially minimally immunogenic or toxic (human sequences and possibly low treatment doses).
- Broad neutralizing activity.
- Mechanism of action less susceptible to resistance.

Development Status:

- Reproducible production and scale-up of chimeric protein has been demonstrated.
- Potent and broad neutralization of genetically diverse HIV–1 clinical isolates was demonstrated.

Market: The race to develop effective antiviral strategies against HIV infection is ongoing. The problems exhibited by conventional drugs (*i.e.* toxicity and resistance) have triggered the pursuit of alternative approaches to HIV/AIDS prevention and treatment. One of the new approaches is the development of neutralizing antibodies against the HIV envelope proteins. This approach has not yet yielded any commercially viable treatment. It is believed that the approach presented in the subject invention will circumvent many of the shortcomings of the existing drugs and other pursued approaches. If this approach is successful the commercial rewards will be huge because of the global magnitude of HIV epidemics.

Inventor: Edward A. Berger (NIAID).

Publication: B Dey, CS Del Castillo, EA Berger. Neutralization of human immunodeficiency virus type 1 by sCD4–17b, a single-chain chimeric protein, based on sequential interaction of gp120 with CD4 and coreceptor. J Virol. 2003 March;77(5):2859–2865.

Patent Status:

HHS Reference No. E–039–1999/0—

- U.S. Patent No. 7,115,262, issued 03 October 2006.
- U.S. Application No. 11/535,957, filed 27 September 2006, published 18 October 2007 as 20070243208.
- Australian Patent No. 765218, issued 30 July 2003.
- Applications pending in Canada, France, Germany, Great Britain, Italy, Japan, Spain.

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D, MBA; 301–435–4616; *ur7a@nih.gov*; RC Tang, JD, LLM; 301–435–5031; tangrc@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Office of Technology Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize ''A Novel Chimeric Protein for Prevention and Treatment of HIV Infection.'' Please contact Rick Williams at 301–402–0960 for more information.

Dated: June 1, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–13284 Filed 6–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0217]

Guidance for Industry on Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events.'' Beginning July 1, 2009, manufacturers of prescription drug products approved under the Federal Food, Drug, and Cosmetic Act (the act) that are required to have a Medication Guide must add a verbatim statement to their Medication Guides containing FDA's toll-free number for reporting side effects. These manufacturers are also required to report to FDA that they have complied with this requirement. This guidance explains what statement to add to Medication Guides, where to add it, and how to notify the agency that such a statement has been added.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5400, *Nancy.Clark@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events.'' On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110–85). Among other things, FDAAA reauthorized the Best Pharmaceuticals for Children Act (BPCA) (Public Law 107–109). When enacted in 2001, the BPCA directed FDA to issue a final rule requiring the labeling of each human drug product for which an application is approved under section 505 of the act (21 U.S.C. 355) to include: (1) A toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for reporting purposes only, not to receive medical advice. The BPCA stated that the final rule must reach the broadest consumer audience and minimize the cost to the pharmacy profession. As required, FDA issued a proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (69 FR 21778, April 22, 2004), which would require, among other things, that a side effects statement be included in FDA-approved Medication Guides for drug products approved under section 505 of the act.

FDA received 22 comments on this proposed rule and was in the process of analyzing the comments and conducting research on consumer comprehension of the side effects statement when FDAAA was enacted. Section 502(f) of FDAAA stated that ''the proposed rule * * * entitled 'Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products' * * * shall take effect on January 1, 2008,'' unless FDA issues a final rule before that date. FDA did not issue a final rule by January 1, 2008, so

as mandated by FDAAA, the provisions of the proposed rule went into effect on that date.

FDAAA mandated one change to the proposed rule. Section 502(f)(2) of FDAAA stated that the toll-free number proposed rule shall not apply to over-the-counter (OTC) drugs marketed with an application approved under section 505 of the act (application OTC drug products) if these application OTC drug products meet certain labeling requirements. Because the agency's rulemaking process was ongoing on January 1, 2008, an interim final rule was issued on January 3, 2008 (73 FR 402) that codified the provisions of the proposed rule as modified by FDAAA. The interim final rule stated that FDA anticipated that affected entities would need time to update labeling and systems to comply with the new requirements and that FDA intended to exercise its enforcement discretion and not take action to enforce the toll-free number requirements in the interim final rule until January 1, 2009. The interim final rule also stated that the agency planned to complete research begun on the proposed labeling statements and would issue a final rule taking into account the results of that research. In the **Federal Register** of October 28, 2008 (73 FR 63886), FDA issued a final rule with an effective date of November 28, 2008, and a compliance date of July 1, 2009. The agency is publishing this guidance to assist manufacturers in complying with the final rule.

This level 1 guidance is being issued for immediate implementation consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA has determined that prior public participation is not feasible or appropriate because the side effects statement is required by Congress and the compliance deadline for its inclusion in Medication Guides is July 1, 2009 (21 CFR 10.115(g)(2)). If comments are received on this level 1 guidance, FDA will review the comments and revise the guidance if appropriate. The guidance represents the agency's current thinking on adding a toll-free number to Medication Guides and reporting this to the agency. 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.

II. The Paperwork Reduction Act of 1995

The required side effects statement is not subject to the Office of Management and Budget (OMB) review under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520) because it is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' and is not considered a collection of information under the PRA (5 CFR 1320.3(c)(2)). The guidance on notifying FDA in the drug's annual report that the side effects statement has been added to the drug's Medication Guide is covered by previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 314.70(d) (changes to an approved application to be described in an annual report) and 314.81(b)(2)(iii)(c) (a summary of labeling changes that have been made since the last annual report) have been approved under OMB control number 0910–0001 for human drugs.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13273 Filed 6–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal Child Health Bureau, Healthy Start Eliminating Disparities in Perinatal Health

AGENCY: Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services.

ACTION: Notice of Non-competitive Supplemental Funding to Northern Manhattan Perinatal Partnership.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing non-competitive supplemental funding under the Maternal Child Health Bureau, Healthy Start Eliminating Disparities in Perinatal Health program to ensure that the Northern Manhattan Perinatal Partnership (NMPP), the primary provider of prenatal services in Central Harlem, can continue to provide much needed services to help stem the rise in and ultimately reduce the Infant Mortality Rate (IMR) in the affected service area.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Northern Manhattan Perinatal Partnership.

Amount of the Non-Competitive Supplemental Funding: $510, 417.

Project Period: The original project period for this grant is through May 31, 2009.

Period of Supplemental Support: June 1, 2009 through January 31, 2010.

Authority: This activity is under the authority of the Public Health Service Act, Section 33OH.

Catalogue of Federal Domestic Assistance Number: 93.926.

Justication for Non-Competitive Supplemental Funding

Northern Manhattan Perinatal Partnership (NMPP), known as Central Harlem Healthy Start, has historically been the primary provider of prenatal services in Central Harlem and has been highly effective in reducing the high rate of infant morality (IMR) in that project/service area. As a consequence of NMPP's leadership and collaborated efforts with other providers in the community, the IMR has declined significantly in Central Harlem since the initiation of the project in 1990 when it was 27.7 infant deaths per 1,000 live births. By 2001, the IMR had dropped to 13.1 infant deaths per 1,000 live births, 54% less than the 1990 rate. The IMR in Central Harlem from 2002 to 2004 showed a decline from the previous years; however, there were fluctuations in the rate of decline in the community. The IMR was at a low of 6.2% in 2002 and increased to 7.3% in 2003, and then in 2004, decreased to 5.1%. The apparent trend in the following two years saw a steady increase to 7.4% for 2005 and 11.2% for 2006. An additional indicator of this trend is the escalating IMR for teen births which saw an increase in the 3 year average from