

June 17, 2008

China – Friend or Foe?

By A. True Ott

Two days ago, my wife and I returned from a week-long Alaska cruise which began and ended in Seattle. Before we left the dock in Seattle, I couldn't help but be amazed at the thousands of sea-containers being unloaded from large barges flying Chinese flags. Each of the sea-containers were marked COSCO (Chinese Offshore Shipping Company) or China Shipping. I guess what amazed me most was that I saw no other foreign ships or containers. It was all China, China, China, at least on the specific dock across from our cruise ship, Holland America Line's Westerdam.

This summer, the Olympics will be held in Beijing. The number eight is very symbolic and sacred to the Chinese people, I understand. It is no coincidence, therefore, that the opening ceremonies are scheduled to begin precisely at 8:08 pm, August, 8, 2008 (8-08-08). (Five sequential eights in Chinese numerology equals pinnacle of destiny.)

In talking to certain individuals in the oil and gas industry, they tell me that the primary reason we are seeing such high fuel prices worldwide is the fact that CHINA is buying all the world's reserves of refined gasoline, and especially diesel as fast as it can be refined --- thus greatly increasing the worldwide demand. WHY does China feel the need to stockpile such a strategic commodity in such a manner? Moreover, should America be concerned?

It should come as no surprise that American retail giants such as Wal-Mart rely HEAVILY on inexpensive Chinese factory goods to make their high profit margins. Of course, the American public is never told that these "goods" are so cheap (and profitable to Sam Walton et, al.) because there is virtually no labor costs. Why are there virtually no labor costs to the Chinese government who had these deals brokered by the LDS Church controlled U.S.-China Business Council? Simply because the labor is supplied by Chinese prison gulags – where literally tens of millions of people are imprisoned and forced to work in the state-run factories. The only Chinese profiting from wild American consumerism is the Communist Party Bosses. Fascism is indeed alive and well. As billions of American dollars continue to flow daily to China – it behooves one to look closer at just how the communist bosses are spending their profits.

In order to expedite the flow of cheap trinkets to American shores, the Clinton Administration saw to it that China owned the strategic Panama Canal and its shipping lanes. Next, the Chinese have been purchasing strategic steel-manufacturing plants from the U.S., and as a result, steel is now being manufactured en masse on the Chinese mainland. Just one such example is Utah-based Geneva Steel's refinery in Lindon, Utah. Once a very integral cog in

heavy equipment parts manufacturing, this once-profitable American refinery is now producing steel for and in behalf of the communist dragon, China.

But wait, we Americans have nothing to fear from this totalitarian, godless regime do we? It really doesn't matter that tens of thousands of Americans died from Chinese guns on the Korean peninsula in a "conflict" that has only a flimsy ceasefire agreement as a basis for the end of hostilities, does it? The Chinese are our friends and partners in the New World Order of Peace, right?

Before answering these questions, one should consider deeply the 2006 speech by one Chi Haotian, China's current minister of defense (the Donald Rumsfeld of China) and Vice-Chairman of China's Central Military Commission. In the following text of his speech, given to China's military leadership, Haotian spoke openly about China's need for "more living space" (ala Adolph Hitler's propaganda) and then stated bluntly that the United States, Canada, and Australia are the only places large enough to accommodate future Chinese needs. Amazingly and chillingly, he notes the need for a quick, effective "biological attack" upon the U.S. to depopulate it as a prelude to conquest, and plainly states that China is working on genetic bio-weapons to kill everyone except "yellow people". He actually boasts proudly of a recent survey conducted by the Chinese military wherein the Chinese public declared that 80% of them would be willing to "shoot and kill women, children and prisoners of war" as part of such an effort against the U.S. Even more startling was his open admission of an ongoing deliberate deception of the U.S. with China portraying itself as a "peaceful business partner" while in reality actually planning to kill "one or two hundred million Americans."

Of course, the esteemed Comrade Haotian also notes that, thanks to huge profits from trade income from Chinese exports, the financing has been provided to "vastly expand Chinese military might" in preparation for an all-out attack upon the U.S. **which he seems to indicate will occur within "five to ten years."**

Also, as you read the text of the speech, also consider the thousands of pet dogs poisoned, and killed by "tainted" dog food from China, and of course, the high-lead paint placed on Chinese-manufactured toys marketed to American children. Consider also that China has quietly purchased over \$1.3 TRILLION in U.S. Treasury Bonds over the last two decades --- enough T-bills to literally buy out Wall-street. The Chinese organized crime syndicate, called the "Triad" is united with the Jewish mob at the highest international levels. Consider that China is the single largest producer of pure HEROIN in the world today, (known on the streets of America as "China White"). Consider that recent reports in California and Texas show that that the "Triad" is responsible for at least 100,000 illegal immigrants entering America annually, and one can get a hint of what their hidden agenda is truly about.

So to summarize:

1. China's Defense Minister announced in his speech (attached) that "100-200 million Americans" would die from a Chinese biological "attack" in the near future. Of course, this would be covert and hidden --- such a "pandemic" would of necessity create panic and financial collapse - where martial law would very likely be declared. Under martial law, all constitutional rights of citizens, all right of habeas corpus, are suspended.

2. Mike Leavitt and Dubya Bush (whose granddaddy Prescott Bush was heavily invested in I.G.Farben which eventually merged into the International Pharma Giant Sanofi-Pasteur) have been very busy the last 3-4 years "preparing" America for a "massive bird-flu (H5N1) pandemic" that would likely kill 100-200 million Americans. Does this seem oddly coincidental?

3. April 17, 2007 - Leavitt's FDA issues an approval letter to pharma giant Sanofi-Pastuer authorizing them exclusively to produce an avian-flu specific vaccine. <http://www.fda.gov/cber/approvltr/h5n1san041707L.htm>
This is highly suspicious to me, considering there have only been 300 cases of H5N1 "avian-flu" WORLDWIDE -- why would Sanofi-Pastuer and the Bush Administration/Mike Leavitt develop such a vaccine, WITHOUT HUMAN TRIALS (see attached FDI letter to Sanofi) unless there was indeed a hidden agenda??

4. On 26 November, 2007, Sanofi expands its influenza vaccine manufacturing facility in: You guessed it --- mainland China. (See In-pharma Newsletter below.) It's goal is to produce 100 million H5N1 bird-flu vaccines a year starting in 2008. (Again, why so many at such a high cost when only 300 worldwide cases 'confirmed'.) And why China? Could it be that the "cost of human trials" not to mention production is so very low or is there another agenda entirely?? Leavitt orders 100 million "Vaccines" from Sanofi-Pasteur --- target date for fulfillment of the order – August, 2008. (See details at www.birdflu.gov)

5. Mutations of the traditional influenza virus cannot naturally become deadly virulent. It takes laboratory assistance and addition of toxic ADJUVANTS in a prepared VACCINE to accomplish this task. In short, the only way for a "pandemic" to occur is if it is pre-planned and lab-induced as a "biological weapon".

6. A perfect opportunity to begin the American pandemic would be to infect American and Canadian athletes at the Olympic Games. What better way to introduce the "vaccine" (i.e. the massive infectious agent) to 150 million Americans than by having its world-class athletes infected??? (How would America react if the entire basketball team became ill with the "bird-flu"?)

7. The HHS "plan" for the American pandemic calls for all law enforcement officials, health care workers, and public servants in ALL 50 STATES to receive the 1ST VACCINES at the first sign of outbreak. In other words, the very people

trained to deal with crisis will be the first ones falling ill. Imagine the anarchy that would cause --- Surely, the Chinese planners are very devious.

8. America would almost welcome Chinese Troops to keep the peace at any cost under such a scenario.

9. China has long been a haven for Satanic High-Level Masons such as Hitler and his motley crew of Bayer-I.G. Farben, New World Order supremacists, and Big Pharma interests in Wall Street. (See Wikipedia entry below.) Reading the text of the Chinese Defense Minister confirms the supremacist mindset of these sicko, godless, soul-less, communists.

10. I have always wondered why the Bush administration would spend billions on "bird-flu" pandemic preparation and training. Could it be the tried and tested Illuminati formula: Problem --- Reaction ---- Solution? (I.e. create the problem -- -- control the reaction ----- then provide the FINAL SOLUTION of a "New World Order".)

11. Does this not constitute HIGH TREASON? Again, bird-flu, like the swine-flu scare of the 1970's can only cause a pandemic if it created, concentrated, then injected purposefully into the population.

Every freedom-loving Christian-American needs to read and re-read Chi Haotian's speech text delivered February, 2006 to all military leaders. The following speech text was recorded and translated by Mr. John R. Rarick, Chairman of the U.S. Day Committee following de-briefing by U.S. Intelligence sources who corroborated its authenticity. (Why has this chilling warning not been debated on "Meet the Press" or any CNN show?? The consistent references by Chi Haotian to Nazi Germany's model of race superiority should be chilling in the extreme to our modern sensibilities.)

"Comrades, I'm very excited today, because the large-scale online survey sina.com that was done for us showed that our next generation is quite promising and our Party's cause will be carried on. In answering the question, "Will you shoot at women, children and prisoners of war," more than 80 per cent of the respondents answered in the affirmative, exceeding by far our expectations.

Today I'd like to focus on why we asked sina.com to conduct this online survey among our people. My speech today is a sequel to my speech last time, during which I started with a discussion of the issue of the three islands [Taiwan, Diaoyu Islands and the Spratley Islands --- Ott] and mentioned that 20 years of the idyllic theme of 'peace and development' had come to an end, and concluded that modernization under the saber is the only

option for China's next phase. I also mentioned we have a vital stake overseas.

The central issue of this survey appears to be whether one should shoot at women, children and prisoners of war, but its real significance goes far beyond that. Ostensibly, our intention is mainly to figure out what the Chinese people's attitude towards war is: If these future soldiers do not hesitate to kill even non-combatants, they'll naturally be doubly ready and ruthless in killing combatants. Therefore, the responses to the survey questions may reflect the general attitude people have towards war.....We wanted to know: If China's global development will necessitate massive deaths in enemy countries, will our people endorse that scenario? Will they be for or against it?

The fact is, our 'development' refers to the great revitalization of the Chinese nation, which, of course, is not limited to the land we have now but also includes the whole world. As everybody knows, according to the views propagated by the Western scholars, humanity as a whole originated from one single mother in Africa. Therefore no race can claim racial superiority. However, according to the research conducted by most Chinese scholars, the Chinese are different from other races on earth. We did not originate in Africa. Instead, we originated independently in the land of China. Therefore, we can rightfully assert that we are the product of cultural roots of more than a million years, civilization and progress of more than ten thousand years, an ancient nation of five thousand years, and a single Chinese entity of two thousand years. This is the Chinese nation that calls itself 'descendants of Yan and Huang.'

During our long history, our people have disseminated throughout the Americas and the regions along the Pacific Rim, and they became Indians in the Americas and the East Asian ethnic groups in the South Pacific. We all know that on account of our national superiority, during the thriving and prosperous Tang Dynasty our civilization was at the peak of the world. We were the centre of the world civilization, and no other civilization in the world was comparable to ours. Later on, because of our complacency, narrow-mindedness, and the self-enclosure of our own country, we were surpassed by Western civilization, and the centre of the world shifted to the West.

In reviewing history, one may ask: Will the centre of the world civilization shift back to China? Actually, Comrade Liu Huaqing made similar points in early 1980's. Based on an historical analysis, he pointed out that the centre of world civilization is shifting. It shifted from the East to Western Europe and later to the United States; now it is shifting back to the East. Therefore, if we refer to the 19th Century as the British Century

and the 20th century as the American Century, then the 21st Century will be the Chinese Century!! (Wild applause fills the auditorium.)

Our Chinese people are wiser than the Germans because, fundamentally, our race is superior to theirs. As a result, we have a longer history, more people, and larger land area. On this basis, our ancestors left us with the two most essential heritages, which are atheism and great unity. It was Confucius, the founder of our Chinese culture, who gave us these heritages. These two heritages determined that we have a stronger ability to survive than the West. That is why the Chinese race has been able to prosper for so long. We are destined 'not to be buried by either heaven or earth' no matter how severe the natural, man-made, and national disasters. This is our advantage. Take response to war as an example. The reason that the United States remains today is that it has never seen war on its mainland. Once its enemies aim at the mainland, the enemies would have already reached Washington before its congress finishes debating and authorizes the president to declare war. But for us, we don't waste time on these trivial things.

Maybe you have now come to understand why we recently decided to further promulgate atheism. If we let theology from the West into China and empty us from the inside, if we let all Chinese people listen to God and follow God, who will obediently listen to us and follow us? If the common people don't believe Comrade Hu Jintao is a qualified leader, begin to question his authority, and want to monitor him, if the religious followers in our society question why we are leading God in churches, can our Party continue to rule China??

The first pressing issue facing us is living space. This is the biggest focus of the revitalization of the Chinese race. In my last speech, I said that the fight over basic living resources (including land and ocean) is the source of the vast majority of wars in history. This may change in the information age, but not fundamentally. Our per capita resources are much less than those of Germany's back then. In addition, economic development in the last twenty-plus years had a negative impact, and climates are rapidly changing for the worse. Our resources are in very short supply. The environment is severely polluted, especially that of soil, water, and air. Not only our ability to sustain and develop our race, but even its survival is gravely threatened, to a degree much greater than faced Germany back then.

Anybody who has been to Western countries knows that their living space is much better than ours. They have forests alongside the highways, while we hardly have any trees by our streets. Their sky is often blue with white clouds, while our sky is covered with a layer of dark haze. Their tap water is clean enough for drinking, while even our ground water is so

polluted that it can't be drunk without filtering. They have few people in the streets, and two or three people can occupy a small residential building; in contrast our streets are always crawling with people, and several people have to share one room. Many years ago, there was a book titled Yellow Catastrophes. It said that, due to our following the American style of consumption, our limited resources would no longer support the population and society would collapse once our population reaches 1.3 billion. Now our population has already exceeded this limit, and we are now relying on imports to sustain our nation. It's not that we haven't paid attention to this issue. The Ministry of Land Resources is specialized in this issue.

But we must understand that the term 'living space' (lebenstraum) is too closely related to Nazi Germany. The reason we don't want to discuss this too openly is to avoid the West's association of us with Nazi Germany, which could in turn reinforce the view that China is a threat. Therefore, in our emphasis on He Xin's new theory, 'Human Rights are just living rights' we only talk about 'living' but not 'space' so as to avoid using the term 'living space.' From the perspective of history, the reason that China is faced with the issue of living space is because Western countries have developed ahead of Eastern countries. Western countries established colonies all around the world, therefore giving themselves an advantage on the issue of living space. To solve this problem, we must lead the Chinese people outside of China, so that they can develop outside of China.

Would the United States allow us to go out to gain new living space? First, if the United States is firm in blocking us, it is hard for us to do anything significant to Taiwan and some other countries! Second, even if we could snatch some land from Taiwan, Vietnam, India, or even Japan, how much more living space can we get? Very trivial! Only countries like the United States, Canada and Australia have the vast land to serve our need for mass colonization.

Therefore, solving the 'issue of America' is the key to solving all other issues. First, this makes it possible for us to have many people migrate there and even establish another China under the same leadership of the CCP. America was originally discovered by the ancestors of the yellow race, but Columbus gave credit to the White race. We the descendants of the Chinese nation are ENTITLED to the possession of the land!!! It is historical destiny that China and United States will come into unavoidable confrontation on a narrow path and fight. In the long run, the relationship of China and the United States is one of a life-and-death struggle. Of course, right now it is not the time to openly break up with them yet. Our reform and opening to the outside world still rely on their capital and technology. We still need America. Therefore, we must do everything we

can to promote our relationship with America, learn from America in all aspects and use America as an example to reconstruct our country.

Only by using special means to 'clean up' America will we be able to lead the Chinese people there. Only by using non-destructive weapons that can kill many people will we be able to reserve America for ourselves. There has been rapid development of modern biological technology, and new bio weapons have been invented one after another. Of course we have not been idle; in the past years we have seized the opportunity to master weapons of this kind. We are capable of achieving our purpose of 'cleaning up' America all of a sudden. When Comrade Xiaoping was still with us, the Party Central Committee had the perspicacity to make the right decision not to develop aircraft carrier groups and focused instead on developing lethal weapons that can eliminate mass populations of the enemy country.

Biological weapons are unprecedented in their ruthlessness, but if the Americans do not die then the Chinese have to die. If the Chinese people are strapped to the present land, a total societal collapse is bound to take place. According to the computations of the author of Yellow Peril, more than half of the Chinese will die, and that figure would be more than 800 million people! Just after the liberation, our yellow land supported nearly 500 million people, while today the official figure of the population is more than 1.3 billion. This yellow land has reached the limit of its capacity. One day, who know how soon it will come, the great collapse will occur any time and more than half of the population will have to go.

It is indeed brutal to kill one or two hundred million Americans. But that is the only path that will secure a Chinese century, a century in which the CCP leads the world. We, as revolutionary humanitarians, do not want deaths, But if history confronts us with a choice between deaths of Chinese and those of Americans, we'd have to pick the latter, as, for us, it is more important to safeguard the lives of the Chinese people and the life of our Party.

The last problem I want to talk about is of firmly seizing the preparations for military battle. The central committee believes, as long as we resolve the United States problem at one blow, our domestic problems will all be readily solved. Therefore, our military battle preparation appears to aim at Taiwan, but in fact is aimed at the United States, and the preparation is far beyond the scope of attacking aircraft carriers or satellites. Marxism pointed out that violence is the midwife for the birth of the new society. Therefore war is the midwife for the birth of China's century."

Sanofi expands flu vaccines in China

By Katrina Megget, In-Pharma Newsletter

26-Nov-2007 - Sanofi-Aventis is to build a new influenza vaccine manufacturing facility in China. An agreement was signed between Chinese Authorities and [Sanofi-Aventis](#) which would allow the building of [Sanofi Pasteur](#) vaccine facility in Shenzhen.

"China is joining a number of countries focussing on prevention of diseases and recognising the value of vaccines. The time is right for Sanofi Pasteur to further invest in [China](#) and prepare to provide this fast growing market with the most modern vaccines to be produced in a state of the industry facility," Sanofi-Aventis chief executive Gerard Le Fur said in a statement.

The plant would be built with the aim of providing a source of [influenza vaccines](#) for the local American population, which could be revved up to produce [pandemic influenza](#) vaccine in China in the event of a human influenza pandemic.

"The Shenzhen government commends this decision to invest in a Sanofi Pasteur influenza vaccine manufacturing facility in Shenzhen. It materialises 10 years of excellent collaboration between Sanofi-Aventis and the Shenzhen government. It is also a milestone in the history of Shenzhen biological industry development," Shenzhen mayor Xu Zongheng said in a statement.

Future investment may be made in the site to keep pace with the anticipated growth of the Chinese vaccine market.

Sanofi Pasteur already operates a facility in Shenzhen.

Back in July, the company completed construction of its new \$150m US facility.

The 140,000sq ft. plant in Swiftwater will see it manufacturing more than 100 million doses of influenza vaccine per year.

FULL STORY AT: <http://www.in-pharmatechnologist.com/news/ng.asp?n=81626-sanofi-aventis-sanofi-pasteur-influenza-vaccines-pandemic-influenza-china>

Wikipedia's entry under the heading "Pharmaceutical Industry in China" tells us more:

Foreign companies

In recent years, more and more western pharmaceutical corporations, such as [GSK](#), [Roche](#), [Novo Nordisk](#), and others, have come to China and set up R&D centers. Many world leading pharmaceutical companies have established [joint venture](#) manufactories in China. Some have even set up sole propriety manufactories. As of 2004, amongst the largest 500 overseas enterprises, 14 of them are pharmaceutical companies.

As of 2004 (three years after China's WTO entry), nearly all global pharmaceutical companies have already completed their accession into the Chinese market and will gradually shift their focus to research development. The main reasons for overseas companies coming to China have been to save costs by using the extensive [science and technology](#) research bases currently in place in China, the abundant [human resources](#), and less expensive medical and [clinical trials](#).

[edit] Foreign production

The involvement of many foreign pharmacy enterprises operating in China can be dated back to a century ago. [Bayer](#) of Germany, the inventor of [aspirin](#), began trade with China in as early as 1882. [Hest](#), known as [Aventis](#), sold its products through 128 distribution agents across China in 1887, becoming China's No.1 Western medicine and dyeing provider. The US [Eli Lilly & Co.](#) opened its first overseas representative office in China's Shanghai in 1918. ICI, the predecessor of the world's No 3 pharmacy enterprise [AstraZeneca](#), began trade with China in 1898, and still maintained its old-time office by the Huangpu River in Shanghai.

As of 2007, there were already 1,800 foreign-funded pharmaceutical enterprises in China [Reference:

<http://www.pacificbridgemedical.com/publications/html/ChinaDec1998.htm>].

Currently, all the top 20 pharmaceutical companies in the world have set up [joint ventures](#) or wholly owned facilities in China. This suggests that market conditions have never been more challenging, with competition at an all-time high.

- [Pfizer](#) produces and markets more than 40 innovative drugs in China, and the quality of its products all met the [Chinese Pharmacopeia](#). Pfizer has [GMP](#) manufacturing facilities in [Dalian](#), [Suzhou](#) and [Wuxi](#). Its Dalian facility, built in 1989 jointly with Dalian Pharmaceuticals was the first to get GMP certification in China. Pfizer has invested more than \$500 million in China.
- [GlaxoSmithKline](#) has more than 2000 employees in China, and its drugs are sold in 60 cities. The company mainly sells drugs treating HBV, asthmas and infections.
- [Merck](#) sells [antibiotics](#), [prostate](#) drugs, [cardiovascular](#) drugs, [pain relievers](#), [osteoporosis](#) and [vaccines](#). It set up its first joint venture in China in 1994.
- [Novartis](#) has invested about 100 million in China, with four manufacturing facilities in Beijing and Shanghai. Its core businesses involve patented drugs, generic drugs, eye protection drugs and health products. Novartis Beijing was founded by Novartis AG and Beijing Pharmaceutical group and Beijing Zizhu Pharmaceuticals in 1987, the first foreign pharmaceutical company in China.
- [Sanofi-Pastuer-Aventis](#) The German-French company sells several drugs in China.

- [AstraZeneca](#) Pharmaceutical Co. has its headquarters in Shanghai, with 25 branch offices in major cities across China's mainland. In 2001, the company established its largest manufacturing site in Asia with a total investment of \$170 million in [Wuxi](#). It sells several products, including [Seroquel](#) and [Nexium](#). It has nearly 3,000 employees working in manufacturing, sales, clinical research and new product development. It has a presence in more than 110 targeted cities, with around 800 representatives.^[1]
- [Bristol-Myers Squibb](#) is one of the earliest to enter Chinese market.

April 17, 2007

Our STN: BL 125244/0

Sanofi Pasteur Inc.
Attention: Gary K. Chikami, MD
Director, Vaccines Establishment
U.S. Regulatory Affairs
Discovery Drive
Swiftwater, PA 18370

Dear Dr. Chikami:

We have approved your Biologics License Application (BLA) for *Influenza Virus Vaccine, H5N1*, effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, *Influenza Virus Vaccine, H5N1*, under your existing Department of Health and Human Services U.S. License No. 1725; however, we acknowledge your statement provided in your submission of April 5, 2007, that Sanofi Pasteur Inc. does not intend to license this product for commercial distribution, since it was produced under contract to the U.S. Department of Health and Human Services as part of national pandemic preparedness initiatives. *Influenza Virus Vaccine, H5N1*, is indicated for active immunization of persons 18 through 64 years of age at increased risk of exposure to the H5N1 influenza virus subtype contained in the vaccine.

Under this authorization you are approved to manufacture *Influenza Virus Vaccine, H5N1* at your Swiftwater, PA facility. Final product filling, labeling, and packaging will be performed at your above facility. The vaccine will be supplied as a suspension in 5 mL multi-dose vials.

The dating period for *Influenza Virus Vaccine, H5N1* shall be 18 months from the date of manufacture of the final container vaccine. The date of manufacture shall be defined as the date on which this monovalent vaccine is filled; thus, the 18-month shelf life is inclusive of the time that the product is held in filled final containers at 2-8°C prior to packaging.

We note that you have submitted samples and Batch Release Protocols for *Influenza Virus Vaccine, H5N1*, bulk Lots U2148, U2149, and U2150. For any other bulk lots that you may have produced or will produce in the future, please submit final bulk samples of the product together with lot release protocols in the proper format showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in the manufacturing, testing, packaging or labeling of *Influenza Virus Vaccine, H5N1*, or in the manufacturing facilities.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We have reviewed your submission dated February 9, 2007, and we deny your full waiver request for pediatric assessment. However, we grant a deferral of your pediatric studies for *Influenza Virus Vaccine, H5N1*, in children less than or equal to 16 years of age.

Postmarketing Studies subject to reporting requirements of 21 CFR 601.70

We acknowledge the postmarketing clinical commitments outlined in your submission of April 5, 2007. These commitments, along with any completion dates agreed upon, are listed below and will provide additional clinical data for the *Influenza Virus Vaccine, H5N1*.

1. You agreed to submit data to assess safety, reactogenicity and immunogenicity of *Influenza Virus Vaccine, H5N1* administered in children.

Protocol submission: Study DMID 04-077: "A randomized, double-blinded, phase I/II, study of the safety, reactogenicity, and immunogenicity of intramuscular inactivated influenza A/H5N1 vaccine in healthy children aged 2 years through 9 years."

Final study report submission: September 30, 2008.

Please note that although your pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are deferred, the deferred status of these required postmarketing studies should be reported as such annually according to 21 CFR 314.81. We will reassess the deferred status of your pediatric studies upon review of the data from the completed pediatric study which you have agreed to submit as a postmarketing commitment listed above.

2. You agreed to provide the final study reports on or before June 30, 2008, as additional data to support immune responses and safety of the *Influenza Virus Vaccine, H5N1*.
- a. Study DMID 04-076: "A randomized double-blinded, placebo-controlled, phase I/II, dose-ranging study of the safety, reactogenicity, and immunogenicity of intramuscular inactivated influenza A/H5N1 vaccine in healthy elderly adults."
 - b. Study DMID 05-0043: "Revaccination of healthy subjects with intramuscular inactivated subunit influenza A/Vietnam/1203/2004 (H5N1) vaccine representing a drifted variant."
 - c. Study DMID 05-0090: "Evaluation of a booster dose of A/Vietnam/1203/04 (H5N1) vaccine administered at 6 months to healthy adult subjects after a two dose schedule at 0 and 1 month."
 - d. Study DMID 05-0129: "Open label evaluation of H5N1 vaccine at vaccine manufacturing facilities."
 - e. Study DMID 05-0130: "A single center, open label, phase I/II study of the safety and immunogenicity of two 90 µg doses of intramuscular inactivated influenza A/H5N1 vaccine in healthy adult subjects."

Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70

We acknowledge the postmarketing commitments outlined in your submission of April 5, 2007 to submit updated stability data as follows.

Please submit non-clinical and chemistry, manufacturing, and controls protocols and all study final reports to your BLA, STN BL 125244. Please use the following designators to label prominently all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Study Protocol**
- **Postmarketing Study Final Report**
- **Postmarketing Study Correspondence**
- **Annual Report on Postmarketing Studies**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted), and
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (<http://www.fda.gov/cder/pmc>). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see <http://www.fda.gov/cber/gdlns/post040401.htm>) for further information.

Please submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and distribution reports as described in (21 CFR 600.81). Under 21 CFR 600.80(c)(2) [Periodic Adverse Experience Reports], you must report each adverse experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals for the first 3 years following approval, and then at annual intervals. Since your product is characterized as a vaccine, you must also submit these reports to the Vaccine Adverse Event Reporting System (VAERS) using the pre-addressed form VAERS-1. Furthermore, we acknowledge your agreement stated in your pharmacovigilance plan and submitted on April 5, 2007, to work with U.S. federal government agencies to design epidemiological studies to assess safety and efficacy of the vaccine and to collaborate to fill gaps in the collection and analysis of important safety, and possibly effectiveness, data in a pandemic situation.

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA-3486 to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling and implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as one original paper copy.

Since, as stated in your April 5, 2007, submission, you do not intend to market this product for commercial distribution, we understand that you will not be distributing promotional advertising or promotional labeling materials. However, should you develop any advertising and/or promotional labeling related to this product (for example, educational brochures), we request that you submit two draft copies with an FDA Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448.

If you have any questions, please contact Dr. Rakesh Pandey at 301-827-3070.

Sincerely yours,

--- *signature* ---

Norman W. Baylor, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research