



Naval Hospital Camp Pendleton

Vaccine Distribution Program

Handbook

Preventive Medicine Department
Immunization Program
Directorate for Public Health Services

NAVAL HOSPITAL
Marine Corps Base Camp Pendleton

January 2008



Welcome to the Naval Hospital Camp Pendleton Vaccine Distribution Program!

As an immunization provider, you are part of a program that has been providing vaccines to the military units and hospital based primary care clinics on this base since 1998. During that time the Preventive Medicine Department of the Naval Hospital maintained a “universal” vaccine distribution program, distributing at no cost all recommended and needed vaccines for military personnel and eventually all primary care clinics within the hospital, attached to and throughout the base.

The Naval Hospital Camp Pendleton Vaccine Distribution Program is supported with one source of funding from the Bureau of Medicine and Surgery. Both the number and the cost of vaccines have increased dramatically over there years along with the need for new vaccines as directed by the Centers for Disease Control and Prevention and the American Council on Immunization Practices. Funding however, has not been able to keep pace with the program that was in place. As of now we are still able to continue to provide vaccines to all units and facilities with a need at “no cost” to support the war fighter and beneficiaries entrusted in our care. Ultimately, however, this escalation in cost, need and type available might lead to future changes in the programs ability to provide vaccines. In order to increase our potential of maintaining this costly program in the future, it is critical that ALL vaccine administrators use and handle each dose of vaccine appropriately. To that end, many of the items discussed in this handbook are focused on assuring vaccine accountability, availability and maintaining vaccine viability.

Thank you for your continued support in our endeavor to provide world class immunizations support to the war fighter and his family.

Naval Hospital Camp Pendleton Vaccine Distribution Program Handbook

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ENROLLING

Enrollment Process
Unit / Facility Types
Changes in Unit / Facility Status
Inactivated Facility Status

Enrollment Process

To receive vaccines from the NHCP Vaccine Distribution Program, you must submit an *NHCP Vaccine Distribution Program Enrollment Contract*. This document contains basic information about your unit or facility and the type and number of estimated patients seen. It is important for you to be accurate when determining your patient profile. Accurately describing your facility size, personnel numbers, contact list, location, need and potential population (military or dependent) allows us to determine how much vaccine you may potentially need. It also serves as a basis for your future funding, our stock levels and ability to obtain and maintain vaccine.

After you submit the NHCP Vaccine Distribution Program Enrollment Contract to the Preventive Medicine Department, you will be informed about your ability or order vaccines.

Unit / Facility Types

As you enroll, you will be asked to designate what type of facility you represent. Please be as complete as possible with all information that is required of the contract at the time of enrollment.

Military Unit vs. Beneficiary Facility

Military Healthcare facilities, for the purpose of this program, are classified and broken down into the categories of Military Unit vs. Beneficiary Facility. In general, this classification breaks out as follows:

Facility Type	Includes these types of facilities
Military Unit	<input type="checkbox"/> Regimental Aid Stations <input type="checkbox"/> Group Aid Stations <input type="checkbox"/> Battalion Aid Stations
Beneficiary Facility	<input type="checkbox"/> Branch Medical Clinic <input type="checkbox"/> Family Practice <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Pediatrics <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Occupational Medicine

Changes in Facility Status

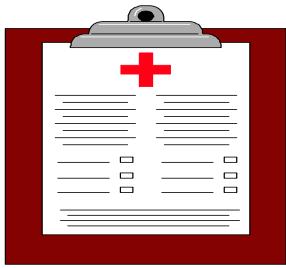
Please contact the Preventive Medicine Department 760-725-1233/1270 if there is a change in your medical facility that may affect your status, including changes in: Immunization providers, loss of individual who originally signed contract, contact personnel, email addresses, physical address or phone number. This helps us ensure our data is current and that you receive your vaccines in a timely manner when you arrive for pick-up, be able to receive recall information in a timely fashion and that the entire process is run in an efficient manner.

Inactivated Certification Status

Certified facilities may be inactivated due to:

1. Facility Request – due to a clinic closure, movement due to construction or deployment. (Please notify the PMD of any closures for record keeping purposes)
2. NHCP Program designation – during certification to participate in the NHCP Vaccine Distribution Program, facilities agree to adhere to federal and state requirements for vaccinations. If at any time it is determined that these requirements or those of the contract are not being followed the PMD may inactivate your facility.

Units / facilities no longer on station due to deployment, relocation are to return all vaccines. Please contact the Preventive Medicine Department at 760-725-1233/1270 for assistance with returns or questions.



CONTRACT

Updating Your NHCP Immunization Program Contract NHCP Immunization Program Contract Terms

Updating Your NHCP Immunization Program Contract

NHCP and Preventive Medicine guidelines require all facilities to update their certification information annually or one of the following circumstances:

1. The senior provider is no longer employed at the listed facility.
2. The majority of the trained providers are no longer with the facility.
3. Significant changes with the facility have happened requiring change.
 - a. Emergency / Power Outage Plan

It is your facility's responsibility to provide the most recent information about your clinic or aid station and an estimate of the number of personnel / dependents your clinic vaccinates.

The NHCP Vaccine Distribution Program will not notify you when it is time to update your contract. In order to maintain current enrollment status, your unit / facility will have approximately 30 days to return the *NHCP Vaccine Distribution Program Contract* or prior to your first order. **If your unit or facility does not submit the necessary registration information, a "hold" will be placed on your facility's vaccine orders.** To order vaccine again, you must submit a current *NHCP Vaccine Distribution Program Contract*.

NHCP Vaccine Distribution Program Contract Terms

The certifying physician or senior member of the medical department of a unit must agree that all staff members will abide by the contract terms listed below:

1. I certify, in administering vaccine received from the NHCP Vaccine Distribution Program for use in my facility / unit. I will provide patients, parents and guardians a copy of the currently approved "Vaccine Information Statement" (VIS) as appropriate before administering each dose of vaccine. I will record the following information in the patients medical record or online medical records system i.e. AHLTA, MRRS.

- Type of Vaccine administered
 - Date vaccine administered
 - Manufacturer name and lot number of the vaccine
 - Location and site of administration
 - Method of administration (intranasal, ID, IM, SC)
 - Signature and professional title of person administering the vaccine
 - Address of the facility in which the vaccine is administered
 - Statement on the issuance of the VIS
2. I will submit the required monthly reports on the current NHCP Immunization Program supplied forms:
- Vaccine Order Form
 - Vaccine Order Form (Influenza)
 - Vaccine Return Form
 - Vaccine Usage Report
 - Copies of temperature logs and / or thermometer graphs from the storage refrigerator(s) and freezer (s) used for vaccine storage.

I understand that my vaccine order will not be filled if the required reports do not accompany my vaccine request.

3. I understand that no more than 50 doses of a single vaccine will be kept on site in our vaccine storage refrigeration units. The only exception to this rule is in the event of a medical readiness stand down in which the Preventive Medicine Department will be notified in writing on the vaccine order form when the order is placed. I further understand that all vaccines remaining 48 hours after a stand down will be returned and any maintenance doses levels needed will be requested at that time.
4. I will return all spoiled or expired vaccines (including partial vials) to the NHCP Immunizations Program along with the completed Vaccine Return Form.
5. I will ensure that all vaccines are maintained at the appropriate temperatures as published in the vaccine product insert and in accordance with Naval Hospital Camp Pendleton instructions. I will ensure that the bulk vaccine storage temperatures are monitored and recorded at a minimum of twice daily and that refrigerator/freezer temperature logs and thermometer graphs are maintained for a minimum of three (3) years. I will have a plan in place to ensure that temperatures are also monitored and recorded at a minimum of twice daily on weekends and holidays through the use of unit or facility duty personnel *without exception*.
6. I will, in accordance with these guidelines, allow the NHCP Immunization Program personnel and the Preventive Medicine Department personnel access to my office for the purpose of conduction Quality Assurance Reviews.
7. {For Varicella vaccine only} I will ensure that:
- My facility has a freezer (with a separate, sealed freezer door) that reliably will maintain an average temperature of +5* F (-15* C) or colder.

- Facility staff are instructed in the special handling requirements of varicella vaccine, and the vaccine will be stored and handles according to the product insert.
8. I will ensure that my vaccine storage refrigerator is approved and of the commercial or laboratory-grade. However, household refrigerator/freezer units with dual controls also may be used to store vaccines. **Dormitory-style refrigerators are not authorized for vaccine storage.** Storage units must be free from any food or drink and labeled accordingly.
 9. I will comply with the appropriate immunization schedule, dosage, and contraindications established by the MILVAX Agency, BUMEDINST 6230.15A, DHHS Advisory Committee of Immunizations Practices (ACIP) and the NHCP Vaccine Distribution Program.
 10. I will comply with the NHCP Immunization Program Fraud, Waste and Abuse policy.
 11. I will maintain a folder with all required information that mirrors that of the NHCP Vaccine Distribution Program to ensure correctness, completeness and accuracy of all orders. This will also enable the unit to maintain historical data on their vaccine program and keep track of all vaccine orders placed along with their status.



Preventive Medicine Department

Vaccine Availability
How to Order Vaccines
When to Order Vaccines
Partial or Short Orders
Vaccine Holds

Vaccine Availability

The Centers for Disease Control and Prevention (CDC) negotiates vaccine prices with manufacturers annually. The military then negotiates prices after that hoping for a reduced price. As a result, occasional changes are necessary in the brand of vaccine supplied or the order in which our orders are processed. The NHCP Vaccine Distribution Program makes every effort to maintain consistency in stocking vaccine brands. Often when the PMD and NHCP Vaccine Distribution Program do not have a particular vaccine or brands it is due to constraints and limitations at a national level. If this occurs, we will make every attempt to locate other brands and manufacturers however, that in and of itself takes time along with the Prime Vendor process.

How to Order Vaccines

Please use the most current version of the *Vaccine Order Form* when placing an order. This will help us correctly identify the vaccines you want and more efficiently process your order. You received a current version of this form with this packet. In addition, the form may be updated periodically to reflect the latest changes in stock. The most current version of the *Vaccine Order Form* may be found by calling the Preventive Medicine Department, stopping by to pick one up or having us email one to your unit or facility. The revision date will be located in the lower right hand corner.

It is simple to order vaccines, but a few things are essential when filling out the *Vaccine Order Form*:

- Fill out ALL of the information at the top of the order form, including your facility name, contact person, title, address, phone number, fax number and pick up dates. 3
- Identify whether these doses are for maintenance levels or a stand down.
- Ensure that if for a stand down that the date for return is clearly marked.
- Circle any information that is new or has changed.
- List your current inventory.
- Write the number of doses of each vaccine you wish to order, keeping in mind that we cannot fill partial orders. (i.e., if a vaccine comes in a 5 dose vial, you should order 5, 10, 15, 20 doses etc. and not 4 or 13.)

- Complete the Vaccine Usage Report and submit at the end of the month. Ensure that the numbers are reflected carefully to ensure your unit / facility is not placed in a hold status. Usage reports may be required on a per order basis.
- Complete the Vaccine Return Form if returning vaccine from a stand down, prior to deployment and for a reduction in levels.
- Bring all necessary forms, copies of temperature logs and graphs to building H-143 when processing your order. The NHCP Vaccine Distribution Program will monitor requests and may adjust orders as well as the endorsing officials may adjust orders according to population size, usage history, current inventory, verified need with MRRS or lack of funds. If vaccines are in short supply or the reported vaccine usage does not support the quantities requested, we reserve the right to reduce vaccine orders.

If you have questions about your vaccine order, please call the Preventive Medicine Department at 760-725-1233/1270. We are open Monday through Friday from 0800 to 1600, excluding weekends and holidays. For return emergencies only the duty Preventive Medicine Technician can be paged at 760-293-0680.

When to Order Vaccines

Your unit / facility must have adequate storage capacity to maintain your ordered supply of vaccine. Vaccine orders are accepted when needed. It normally takes 72 hours to fill an order after it is introduced into the approval chain. However, it may take up to 2 weeks for an order to be processed during periods of high demand or when orders of a single item are in excess of 200 doses. Planning ahead and contacting the PMD in advance is always good business practice prior to making large orders. It is not always possible to accommodate rush orders, so it is important to take inventory of your stock, know your stand down dates, plan and order accordingly. **Do not wait until you are almost out of a vaccine before ordering.** Place another order when you have low maintenance levels on hand and inventories are minimal. Please remember DO NOT place a vaccine order or pick up if your facility is going to be close for a holiday, extended vacation or on Fridays before long weekends.

Partial or Short Orders

If you receive an incomplete, partial or short order due to stock limitations update your records. This will be beneficial to ensuring you place the proper order subsequently when stock levels rise. It is recommended to keep ALL forms on hand and in the administrative folder that is brought when picking up vaccines.

Vaccine “Holds”

If your unit / facility has been identified as having inadequate storage, an excessive amount of a vaccine wastage (5% or more vaccine lost/year), or another program violation, a temporary “hold” on vaccine ordering may be activated. To have the “hold” lifted, your unit / facility must contact the Preventive Medicine Department and demonstrate that the necessary corrective action(s) have been taken.



Inventory

Storage and Handling
Temperatures
Rotating Stock
Accountability
Vaccine Returns

Storage and Handling

Your unit / facility must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All staff members must know how to store vaccine and what to do with it upon arrival and if left out.

- Educate staff members about vaccine pick-ups. This is imperative so that vaccines are identified and stored in the refrigerator or freezer as soon as they are brought back. NHCP Preventive Medicine Department will be conducting courses. Please contact for further information.
- Unpack vaccines in a timely manner. Check the temperature indicator inside, if one is placed inside, to be sure the vaccine arrived within the correct temperature range.
- Keep copies of your *Vaccine Order Forms* and *Return Forms*.

When possible, providers should use commercial or laboratory-grade refrigerators for vaccine storage. However, household refrigerator/freezer units with dual controls also may be used to store vaccines. **Dormitory-style refrigerators are not recommended for vaccine storage.** Storage units must be free of any food or drink.

Your unit / facility are required to develop a written *Emergency Response Plan* outlining your methodology to ensure vaccine will be appropriately handled in the event of a power failure. All staff must be familiar with your site specific *Emergency Response Plan*, which should be posted on/near your vaccine storage unit and updated annually.

Temperatures

Bulk storage refrigerators and freezers (i.e., the main storage units in the facility) must be monitored using appropriately calibrated thermometers. The temperatures must be recorded at a minimum of **twice daily** to ensure appropriate vaccine storage temperatures are being maintained. The NHCP Vaccine Distribution Program now requires temperature logs and thermometer graphs be retained for a minimum of three (3) years. Thermometers should be placed as close to the vaccine stock as possible. This will allow the thermometer reading to more closely reflect the actual temperature of the vaccine.

(Some areas of the refrigerator – for example, in the door or near the sides – may hold warmer temperatures than the center where the vaccine is properly stored.) **Be sure that you do not place either the vaccine or the temperature monitor directly under the outlet that blows air from the freezer into the refrigeration area.** Placing water bottles or gel packs in the refrigerator and gel packs in the freezer may help stabilize internal temperatures should power outages occur.

It is important to document each corrective action whenever temperatures are adjusted. Notify the Preventive Medicine Department at (760-725-1233/1270) if temperatures are outside the acceptable range for your vaccines for ANY amount of time.

Rotating Stock

Rotate your stock so that the vaccine closest to expiration is used first. Upon picking up an order of vaccine, check expiration dates and store the vaccine in the refrigerator/freezer so that vaccine with the earliest expiration date is in front of vaccine with a later expiration date.

Accountability

In addition to temperature monitoring information, certified providers must submit three (3) reports each month to account for all vaccines received from the Alaska Immunization Program as either: (1) in inventory, (2) used, (3) returned or (4) loss.

Vaccine Order Form – This form includes a column to list your current inventory of vaccines.

Vaccine Usage Report – This report provides the total number of doses of vaccines administered by your unit / facility during the designated time period.

Vaccine Return Form – Any vaccines that have expired or have been spoiled, or wasted should be documented on this form.

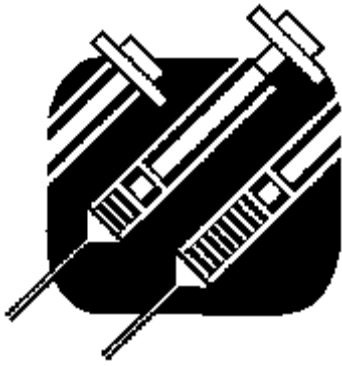
Vaccine Loss Statement / Incident Report – All vaccines that have been lost due to negligence are reported on this form. Also, these forms are to assist in identifying areas of concern, identify what happened and what corrective action must be taken. Ensure that the endorsement is submitted through the proper chain for notification.

Vaccine Returns

Report any expired, lost, spoiled, or wasted vaccine by including a *Vaccine Return Form or Vaccine Loss Statement* when vaccines are returned to the Preventive Medicine Department. After your return is received and verified, your facility record will be credited with the actual number of doses received in a good useable state.

Viable Vaccines – Be sure to have all of the proper forms and transportation methods available for before returning any viable vaccines.

Non-viable vaccines – Return these vaccines **in a box that will minimize potential breakage during transport and separate from good vaccine**. If these are packed by themselves and no other vaccines are in the container then cold packs are not required.



Quality Assurance Reviews

What are QA Reviews?
Standards Used to Conduct QA Reviews
Types of QA Visits
Frequency of QA Reviews
Requesting a QA Review

What are QA reviews?

NHCP's new guidelines require that Preventive Medicine staff be allowed to conduct Quality Assurance (QA) Reviews at each enrolled unit / facility in deemed necessary. During the review, an evaluation of your procedures and adherence to NHCP Immunization Program Standards will be reviewed including vaccine storage conditions.

Reviews will be scheduled by phone at least two weeks prior to the desired visit date. These visits are designed to assist you in the quest for success and not a means of "catching" a unit or facility in the wrong, this is an "opportunity". After scheduling a QA Review, your Naval Hospital Camp Pendleton Preventive Medicine Technician staff will answer any questions you may have regarding the visit. After the QA Review is conducted, you will be provided a report that outlines each QA standard and details your unit's / facility's compliance. The recommendations in the report should be implemented immediately for you to be in compliance with program guidelines and the requirements of your contract.

Standards Used to Conduct QA Reviews

The NHCP Vaccine Distribution Program supports six (6) quality assurance standards for immunization distribution / provider activities. These standards will be reviewed during site visits conducted by Preventive Medicine Department personnel.

1. Vaccines are properly documented.

- Ensure an adequate supply of vaccines are on hand to maintain daily operations and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines, for example Anthrax. Providers are required to document the following items for each vaccine given:

- Type of Vaccine administered
- Date vaccine administered
- Manufacturer name and lot number of the vaccine
- Location and site of administration
- Method of administration (intranasal, ID, IM, SC)
- Signature and professional title of person administering the vaccine
- Address of the facility in which the vaccine is administered
- Statement on the issuance of the VIS

This information will be recorded with the above information in the patients medical record or online medical records system i.e. AHLTA, MRRS.

2. Providers must explain the contraindications and inform patient, parent or guardian of risks and benefits of vaccination to be received before administering vaccine.

- As required under the National Childhood Vaccine Injury Act, all health care providers in the United States who administer any vaccine shall, prior to administration of each dose, provide a copy of the relevant current editions of the Vaccine Information Statements (VIS) produced by the Centers for Disease Control and Prevention (CDC).

- The VIS shall be provided to the parent or legal representative of any child to whom the provider intends to administer such vaccine. If you are unable to obtain, contact Preventive Medicine or check the resources section of this handbook.

- Health care providers must make a notation of the publication date of the VIS, in each patient's permanent medical record at the time the VIS is provided.

- The National Childhood Vaccine Injury Act also requires providers to take additional measures to inform patients or parents of risks (i.e., precautions, contraindications, side effects, and previous adverse events) and benefits of the vaccine.

3. Vaccines are administered according to guidelines.

- Providers in the NHCP Vaccine Distribution Program are to administer vaccines in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP) and NHCP Immunization Program guidelines.

- The ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention. The Committee develops written recommendations for the routine administration of vaccines to the pediatric and adult population, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government that makes such recommendations.

If there are any questions that are not answered here, please if able, refer to the Naval Hospital Camp Pendleton Immunizations Manual by contacting the commands Immunizations Program Manager, Mrs. Jennifer Holder at 760-725-3513.

**4. Providers make every attempt to ensure all patients are up to date on immunizations.
“Unit and Individual Medical Readiness Depends on this Success”**

- Providers do everything possible to obtain the military members or dependent complete immunization history.
- Transcribing immunization histories to a single form is highly recommended. Ensure that all computerized databases i.e. MRRS is complete for military active duty units.
- Immunization records should be reviewed at each visit to identify needed vaccinations, and the patient or guardian needs to be reminded during their visit of when the next immunization visit is due.
- A recall system to identify personnel needing vaccination and stand down practices needs to be in place to ensure readiness is a top priority.

5. Appropriate use and completion of all NHCP Vaccine Distribution Program forms.

- Once a year each unit / facility will be required to fill out another form and recertify their unit or facility. In order to maintain current enrollment status, your facility will have approximately 15 days to return the certification form to the Preventive Medicine Department office. If your unit or facility does not comply, a “hold” will be placed on that unit or facility’s vaccine orders and you will need to submit the certification forms to release the hold.
- All units and facilities must submit a *Vaccine Usage Report* in addition to temperature monitoring information with each order.

6. Vaccines are stored and monitored to ensure viability and proper usage.

- Vaccines must be stored under the appropriate conditions.
 - Refrigerated vaccines: 35° – 46° F (2° - 8° C)
 - Frozen vaccines: +5° F (-15° C) or below
- Bulk vaccine refrigerator/freezer storage units must have a thermometer to monitor temperatures.
- Temperatures of both the refrigerator and freezer must be recorded at least a minimum of **twice daily** on days facility is staffed. Temperatures are also to be taken at least a minimum of **twice daily** on weekends and holidays by duty staff personnel. Address this within the Emergency Plan as well as the chain of command to ensure compliance with the contract and ensure safety of the vaccines.
- Facility must have a written Emergency Response Plan for vaccine storage in the event of power or mechanical failure.
- Vaccine stock is rotated to assure the earliest expiration date is used first.
- Vaccines are stored on the shelves of the refrigerator or freezer, not in the door.
- Vaccines are stored in a refrigerator or freezer that is free of food and drink.
- Vaccine stock must be monitored carefully to keep vaccine wastage to less than five percent (5%) of ordered vaccine.

Types of QA Visits

Quality Assurance Visit: This will be the most common type of visit performed by the Preventive Medicine Department personnel. The visit consists of an examination of vaccine storage and handling, and a QA evaluation with the designated point(s) of contact. This type of visit typically lasts around one to two hours. The majority portion of this time is spent conducting interviews with the staff.

Educational Visit: While all visits are designed to be educational, this type of visit is conducted for anyone who wishes to learn more about immunizations or the NHCP Vaccine Distribution Program in general. These visits can be tailored to fit a unit's individual needs/requests and can last anywhere from less than an hour to several hours.

Frequency of QA Reviews

QA Reviews generally are performed annually at each unit or facilities location, but they may occur at any time. PMT's may schedule additional reviews if they feel they are warranted for additional vaccinator or provider education.

Requesting a QA Review

The Preventive Medicine Department is always happy when providers wish to learn more about our Program or immunizations in general. To request an NHCP Distribution Program visit, please contact (760) 725-1233/1270.

Resources

Preventive Medicine Department, Naval Hospital

Ph: (760) 725-1233/1270

Fax: (760) 725-0564

National Center for Immunizations and Respiratory Diseases (CDC) (formerly – National Immunization Program)

<http://www.cdc.gov/nip/>

1-800-CDC-SHOT – For information on vaccines licensed for use in the United States, immunization schedules and publications on vaccine-preventable diseases.

1-800-232-0233 – A Spanish hotline providing materials and services to callers with questions about immunizations.

Vaccine Adverse Event Reporting System (VAERS)

<http://www.vaers.hhs.gov/>

1-800-822-7967

U.S. Vaccine Manufacturers (Vaccine Information Websites)

GlaxoSmithKline <http://www.gsk.com/products/vaccines.jsp>

Merck <http://www.merckvaccines.com>

MedImmune <http://www.medimmune.com/products/flumist/index.asp>

Novartis <http://www.novartisvaccines.com>

sanofi <http://www.vaccineplace.com>

Wyeth <http://www.wyeth.com/products?condition=vaccines>

BUMEDINST 6230.15A – Immunizations and Chemoprophylaxis

http://www-nehc.med.navy.mil/downloads/prevmed/BUMEDINST_6230_15A_29_SEP_06.pdf