## Dragon, Karen E. (CDC/NIOSH/EID)

**From:** Debora Van der Sluis [vandersluis.debora@gene.com]
**Sent:** Thursday, September 20, 2007 4:59 PM
**To:** NIOSH Docket Office (CDC)
**Subject:** NIOSH Hazardous Drugs List Update. Docket Number NIOSH 105

**Attachments:** PublicReviewForm2006-05-01-07_Genentech, Inc..xls; ATT757056.txt; Genentech comments to NIOSH_20Sept07.doc; ATT757057.txt


PublicReviewForm2006-05-01-07_...


ATT757056.txt (68 B)


Genentech nments to NIOSH_2


ATT757057.txt (195 B)

Ms. Miller,

The following comments are being submitted to NIOSH Docket 105, per Federal Register 72 FR 33507; 18 June 2007.

September 17, 2007

Ms. Diane Miller
Robert A. Taft Laboratories
National Institute for Occupational
Safety and Health
4676 Columbia Parkway
MS C-34
Cincinnati, OH 45226

Re: NIOSH Hazardous Drugs List Update; Federal Register 72 FR 33507; 18 June 2007
[Docket Number NIOSH 105]

Dear Ms. Miller:

Genentech, Inc. (Genentech) wishes to thank NIOSH for allowing us to submit comments on the approach to updating "Appendix A. Drugs Considered Hazardous" of the "NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings," (Hazardous Drug Alert) DHHS Publication No. 2004-165 (2004). The Federal Register Notice (72 FR 33507, June 18, 2007) also requests comments on the definition of hazardous drugs, in apparent contradiction with the NIOSH web site; we are providing these as well. The handling of hazardous drugs is an important issue for healthcare workers and Genentech supports the efforts NIOSH has taken to update the Hazardous Drugs List and the definition of a hazardous drug. We appreciate the opportunity to submit comments, and your inclusion of representative stakeholders, including manufacturers of biotherapeutics, in this process.

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Over sixteen of the currently approved biotechnology products originated from or are based on Genentech science. Our key products have been recombinant proteins, including monoclonal antibodies, unique (as compared to previously employed synthetic) biologic therapies for the treatment of human diseases. Genentech was the first to produce a human protein and the first to clone human insulin using recombinant DNA technology.

Protropin® was the first recombinant biotechnology drug manufactured and marketed by a biotechnology company. Rituxan® (rituximab), approved November 26, 1997, was the first therapeutic antibody approved for cancer in the U.S. and Herceptin® (trastuzumab), approved September 25, 1998, was the first therapeutic antibody approved for metastatic breast cancer. Our company is committed to high standards of integrity in contributing to the best interests of patients, the medical profession, our employees, and our communities, and a core value is the continual pursuit of scientific and operational excellence.

The scientific accuracy of the Hazardous Drug Alert is an important aspect of health care worker occupational health and safety programs and hazard communication. If the scientific evidence for handling a hazardous drug in a particular manner is not supportable, and is not harmonized with handling recommendations of the U.S. Food and Drug Administration (FDA) and risk assessment approaches defined by other expert groups (see further references described in our comments below), then risk decisions and hazard control measures taken by employers and employees in health care settings will not be appropriate. We therefore request the following recommendations be adopted and modifications made to the Draft NIOSH Alert based on the scientific evidence.

## General Comments

1. **Lists of Drugs "Fitting" and "Not Fitting" the NIOSH Criteria**- On the NIOSH web site, there are two lists for which comments are solicited: "New FDA Drugs and Warnings Not Fitting NIOSH Criteria for Hazardous Drugs 2006" and "New FDA Drugs and Warnings Fitting NIOSH Criteria for Hazardous Drugs 2006." It is unclear what specific reasons there are for the conclusion that a particular drug is "Fitting" or "Not Fitting" the criteria based on the information provided in the charts. It does not appear that the published definition (NIOSH, 2004) was used in the assessment of current candidate drugs, and this was confirmed in the August 28, 2007 Public Meeting, i.e., a qualitative approach was followed. It would be very helpful for the healthcare community, the public, and other stakeholders, to understand the bases for the conclusions for each drug.

**Recommendation:** NIOSH should provide the specific basis for each conclusion that a drug is identified either as "fitting one or more characteristic of hazardous drug as defined by NIOSH" or "did not meet the NIOSH criteria."

2. **Low Dose Exposures in the Definition of Hazardous Drugs**- NIOSH should continue to more directly relate low-dose effects of hazardous drugs to the hazard categories of organ, developmental and reproductive toxicity. A low dose effect is a daily therapeutic dose of 10 mg/day or less, or a dose of 1 mg/kg per day or less in laboratory animals, that causes serious organ toxicity, developmental toxicity, or reproductive toxicity.

   **Recommendation:** NIOSH should place additional focus on relating adverse health effects to low-dose exposures or exposure limits, so that only the subset of drugs that require special handling are included on the hazardous drug list.

3. **Risk Assessment and Risk Management: Large Molecular Weight Proteins**
   Hazard identification, the approach of the NIOSH Alert, is a simplistic method that does not consider exposure or the potential for absorption, bioavailability and dose-response of drugs. To assure scientifically sound guidelines on the potential risk to healthcare workers handling hazardous drugs, it is critical that these be taken into account. If they are not, many drugs, such as large molecular weight biotherapeutics which include monoclonal antibodies that are administered intravenously or subcutaneously, by default, will meet the NIOSH criteria for a hazardous drug as currently defined, but will not present a true risk to healthcare workers. In healthcare settings, the primary routes of exposure to hazardous drugs are respiratory and dermal. Large molecular weight proteins, e.g., monoclonal antibody, therapeutics can only have a significant pharmacologic effect when deliberately introduced into a person's body by a parenteral route and absorbed into the systemic circulation, or possibly if specifically engineered to be absorbed by the lungs (Blink, 2007). With molecular weights ranging from 100-150 kD and a particle size of $\geq$ 10 microns,

there is general agreement that there is an extremely low likelihood of absorption following dermal or inhalation exposure in the workplace.

Based on these considerations, Genentech encourages NIOSH to consider and, to the extent possible, be consistent with guidance put forth by other expert groups. We are concerned that if the scientific evidence for handling a hazardous drug in a particular manner is not supportable, and is not harmonized with other expert groups, then risk decisions and hazard control measures by employers and employees in health care settings will not be appropriate and will not reflect the actual, potential hazards that exist. Specifically, the British Centralized Intravenous Additives Group (CIVAS) and the British Oncology Pharmacy Association (BOPA) have made the following joint statement regarding the handling of monoclonal antibody therapeutics the class of compounds, (that are non-conjugated and non-radiolabeled) (CIVAS/BOPA, 2001) excerpted below.

> "Although genetic engineering techniques are used to produce humanized antibodies, those in current use are not designed to interact directly with the recipient's genetic material…
>
> They do not interact directly with the transcription of DNA or RNA and would not be expected to be mutagenic or teratogenic…
>
> As a class, these do not require specific facilities for their safe handling since they pose no special risk to the operator or the environment. Therefore, they can be handled in the same facilities as those for other aseptic products. Those presently used routinely do not appear to be carcinogenic or teratogenic and so they can be handled in the same facilities used for non-cytotoxic aseptic products."

A better, more scientifically-based approach to risk assessment could be based on the well-accepted methodology of the U.S. Environmental Protection Agency (EPA). EPA has a long history of using the basic principles and practice of risk assessment to ensure appropriate risk management and this approach could be easily used by NIOSH. Risk assessment has been defined as "the characterization of the potential adverse health effects of human exposures to environmental hazards" (NRC, 1983). According to EPA, risk assessment is "the extent to which a group of people has been or may be exposed to the kind and degree of hazard posed by a chemical, thereby permitting an estimate to be made of the present or potential health risk to the group of people involved" (EPA, 2007). Risk assessment information (from the process of hazard identification -> dose-response assessment -> exposure assessment -> risk characterization) is then used in the risk management process to implement administrative and engineering controls to protect people.

**Recommendation:** NIOSH should ensure that the information on large molecular weight proteins in the Hazardous Drug Alert accurately reflects the hazards that exist to healthcare workers and is consistent with well-accepted principles of risk assessment and risk management to avoid confusion for both employers and employees. Warning of a hazard unlikely to be faced may take attention and resources away from hazards more likely to be present in the workplace.

## Specific Comments

***Based on the existing scientific and clinical evidence, we strongly recommend that NIOSH delete rituximab from the list of "New FDA Drugs and Warnings Fitting NIOSH Criteria for Hazardous Drugs 2006"***

Genentech is concerned that our commercial drug, Rituxan® (rituximab) is on this list but does not meet the NIOSH criteria for a "hazardous drug" stated in the Hazardous Drug Alert. The scientific evidence for deleting rituximab from the list of hazardous

drugs is strongly supported by the available toxicological and clinical data summarized below:

Drugs that are considered hazardous include those that exhibit one, or more, of the following six characteristics in humans or animals:

1. Carcinogenicity- Rituximab has not been tested for its carcinogenic potential. Its pharmacological mechanism of action (it binds to the antigen CD20, which regulates the activation process for cell cycle initiation and differentiation, and causes lysis of the B-lymphocytes by activating the complement cascade and immune effector cells and inducing apoptosis) would not suggest it to be carcinogenic. No human cancers directly attributable to rituximab were reported in clinical studies).
2. Teratogenicity or other developmental toxicity- In studies in non-human primates, rituximab was not found to be a teratogen or developmental toxicant. In a reproductive toxicity study (Genentech Study 01-483-0346), rituximab at doses of 20, 50, or 100 mk/kg were given weekly to pregnant female cynomolgus monkeys during the period of organogenesis. There were no findings of toxicity to the dams or developing fetuses, and the only effect noted was the dose-dependent pharmacologic depletion of B cells in the lymphoid organs of the fetuses.
3. Reproductive toxicity- Repeated dose studies in laboratory animals have not indicated the reproductive system to be a target organ of toxicity, and pharmacological studies do not indicate that the reproductive system organs would bind rituximab (a monoclonal antibody specific for IgG)).
4. Organ toxicity at low doses- Rituximab has some toxic properties including hematological effects but, at a clinical dose

of 375 mg/m$^2$, or approximately 700 mg/dose, it does not meet the low dose criteria in the NIOSH Alert;

5. Genotoxicity- Although not studied, there are no data to suggest rituximab is genotoxic as per the International Conference on Harmonization (ICH) guideline for testing of pharmaceuticals [see further information below[1]]; genotoxicity / mutagenicity studies are not generally performed. For rituximab, the mechanism of action of the drug would preclude it from entering the cells used to assess mutagenic endpoints; and
6. Structure and toxicity profile of new drugs that mimic existing drugs that are hazardous by the above criteria- Rituximab is a monoclonal antibody. As a class of targeted and specific therapies to prevent cancer, they do not mimic the traditional cytotoxic, antineoplastic cancer chemotherapy treatments, which would be considered hazardous.

We strongly believe that rituximab should NOT be included on any list of hazardous drugs. This belief is also supported by the U.S. Food and Drug Administration's (FDA's)-required labeling of this commercial biotherapeutic. After a thorough review of Genentech's clinical and toxicology data, no requirement to apply precautionary special handling labeling, as would occur for traditional cytotoxic, antineopleastic cancer chemotherapy treatments, has been mandated by FDA (Rituximab, 2007). The Center for Drug Evaluation and Research (CDER) of FDA has a policy, as cited in several letters to manufacturers (www.fda.gov search term - cytotoxic labeling policy), that requires references for safe handling of antineoplastic and cytotoxic drugs be included in the labeling. These are not required for rituximab as it does not meet the criteria for requiring this labeling by FDA.

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[1] The ICH Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (56), 16 July 1997 (pg.8) states:

"The range and type of genotoxicity studies routinely conducted for pharmaceuticals are not applicable to biotechnology-derived pharmaceuticals and therefore are not needed....It is not expected that these substances would interact directly with DNA or other chromosomal material."

We are also concerned that rituximab, deleted by NIOSH in 2004 from the original "sample" list of hazardous drugs- because it did not meet the criteria for a hazardous drug (refer to the letter from Dr. J. Howard, Director of NIOSH, dated June 14, 2004)- has again been included in the current list. We understand that the current re-listing was based on a decision of a review group who believed that new safety warnings for Rituxan® warranted this. We would appreciate an opportunity to address these new concerns about rituximab.

## Conclusion

We believe that since NIOSH is a highly respected Agency, known for its scientific rigor, it is essential that the information developed be scientifically supported and consistent with the listing criteria. Genentech urges NIOSH to consider our recommendations and supporting data, and believes that the inappropriate listing of monoclonal biotherapeutics as drugs hazardous for workers in healthcare settings dilutes the important information provided on drugs that truly meet the criteria for "hazardous". This hazard identification approach will also dilute the impact of and be inconsistent with the warnings, precautions, controls and recommendations for the drugs that require such handling for worker protection; healthcare workers may now believe that rituximab and other large molecular weight proteins could be harmful to their health. Although we do not know to what extent, this listing will clearly have a negative impact on our patients, employees, and the healthcare workers who handle and administer our biotherapeutics to millions of people worldwide. We take our mission- to discover and bring to market new, innovative products that address previously unmet medical needs- seriously and our company culture fully supports this goal. Genentech believes the scientific data firmly establishes the need to de-list rituximab and other large molecular weight therapeutics.

Thank you for your consideration. If there are questions regarding our comments, please contact me.

Respectfully submitted,

Gene Murano, Ph.D.
Vice President Regulatory Affairs,
1 DNA Way,
South San Francisco,
CA 94080
(650-225-7855)

***References***

Blink, R.C. (2007) Concepts of Occupational Exposure to Monoclonal Antibody. WorkCare, Inc. September 9.

CIVAS/BOPA (2001) Monoclonal Antibodies. Hospital Pharmacist, 8:153, June.

EPA (Environmental Protection Agency) (2007) Integrated Risk Information System. http://www.epa.gov/iris/intro.htm, Washington, D.C., September 17.

Gebhart, F. (2007) NIOSH to Update Hazardous Drug List, Drug Topics, February 5.

NIOSH (National Institute for Occupational Safety and Health) (2004) Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings. DHHS Publication No. 2004-165.

NRC (National Research Council) (1983) Risk Assessment in the Federal Government: Managing the Process. National Academy Press, Washington, D.C.

Rituximab (Rituxan®) FDA approved labeling, 2007, Genentech, Inc.

| Drugs to Review 2006 Docket #NIOSH-105 | | | | Send reviews to: niocindocket@cdc.gov |
|---|---|---|---|---|
| Reviewer : Debora Van der Sluis | | | | |
| Affiliation : Genentech, Inc. | | | | |
| **Proprietary Name** | **Established Name** | **Should this Drug be Included in the NIOSH Hazardous Drugs List ?** | | **Comments** |
| | | **yes** | **no** | |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Abilify | aripiprazole | | | |
| Alimta | pemetrexed | | | |
| Amevive | alafacept | | | |
| Amitiza | lubiprostone | | | |
| Apokyn | apomorphine HCl | | | |
| Arranon | nelarabine | | | |
| Avastin | bevacizumab | | | |
| Azilect | rasagiline mesylate | | | |
| Baraclude | entecavir | | | |
| Chantix | varenicline | | | |
| Clolar | clofarabine | | | |
| Cordarone | amidarone HCl | | | |
| Dacogen | decitibine | | | |
| Depacone | valproate Na | | | |
| Depakene | valproic acid | | | |
| Depakote | divalproex Na | | | |
| Depo-Provera** | medroxyprogesterone acetate | | | |
| Elidel | pimecrolimus | | | |
| Erbitux | cetuximab | | | |
| Geodon | ziprasidone | | | |
| Gleevec | imatinib mesylate | | | |
| Hivid | zalcitibine | | | |
| Hycamtin | topotecan HCl | | | |

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| **Proprietary Name** | **Established Name** | **Should this Drug be Included in the NIOSH Hazardous Drugs List ?** yes | no | **Comments** |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Increlex | mecasermin (rDNA origin) | | | |
| Kepivance | palifermin | | | |
| Leustatin | cladrabine | | | |
| Lunesta | eszopicline | | | |
| Lyrica | pregagalin | | | |
| Metastron | strontium-89 chloride | | | |
| Mycamine | micafungin sodium | | | |
| Myozyme | alglucosidase alfa | | | |
| Nexavar | sorafenib | | | |
| Orencia | abatacept | | | |
| Paxil | paroxetine HCl | | | |
| Pentetate Calcium Trisodium | | | | |
| Photofrin | porfimer sodium | | | |
| Provera** | medroxyprogesterone acetate | | | |
| Quadramet | samarium 153 lexidronam | | | |
| Rapamune | sirolimus | | | |
| Revlimid | lenalidomide | | | |
| Risperdal Consta** | risperdone | | | |
| Risperdal** | risperidone | | | |
| Rituxan | rituximab | | X | Refer to Letter from Dr. Gene Murano, Vice President, Regulatory Affairs, dated September 20, 2007 (submitted to NIOSH Docket 105 at niocindocket@cdc.gov) |

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| | | **yes** | **no** | |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Rozerem | ramelteon | | | |
| Seroquel | quetiapine fumerate | | | |
| Spiriva Handihaler | titropium bromide | | | |
| Sprycel | dasatinib | | | |
| Sustiva | efavirenz | | | |
| Sutent | sunitinib malate | | | |
| Tarceva | erlotinib HCl | | | |
| Tindamax | tinidazole | | | |
| Tracleer | bosentan | | | |
| Trileptal | oxcarbazepine | | | |
| Tygacil | tigcycline | | | |
| Tysabri | natalizumab | | | |
| Velcade | bortizomib | | | |
| Vidaza | azacitidine | | | |
| Viramune | nevirapine | | | |
| Viread | tenofovir | | | |
| Vision Blue | trypan blue | | | |
| Zolinza | vorinostat | | | |
| Zonegran | zonisamide | | | |
| | | | | |
| **New FDA Drugs and Warnings Not Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Actoplus Met | pioglitazone HCl/ metroformin HCl | | | |

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| Proprietary Name | Established Name | Should this Drug be Included in the NIOSH Hazardous Drugs List ? yes | no | Comments |
| New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs | | | | |
| Actos | pioglitazone HCl | | | |
| Adderall | amphetamines | | | |
| Amphadase** | hyaluronidase | | | |
| Apidra | insulin glulisine | | | |
| Aptivus | tipranivir | | | |
| Aranesp | darbepoetin alfa | | | |
| Avandaryl | rosiglitazone maleate/ glimepiride | | | |
| Avonex | interferon beta 1a | | | |
| Betaseron | interferon beta 1b | | | |
| Byetta | exenatide | | | |
| Campral | acamprosate calcium | | | |
| Cancidis | caspofungin acetate | | | |
| ChiRhoStim | human secretion | | | |
| Clozaril | clozapine | | | |
| Concerta* | methylphenidate HCl | | | |
| Cymbalta | duloxetine HCl | | | |
| Daytrana* | methylphenidate HCl | | | |
| Dexedrine | dextroamphetamine | | | |
| Dilaudid | hydromorphone HCl | | | |
| Diovan | valsartan | | | |
| Elaprase | idursulfate | | | |
| Elmiron | pentosan polysulfate Na | | | |

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| Affiliation : Genentech, Inc. | | | | |
| **Proprietary Name** | **Established Name** | **Should this Drug be Included in the NIOSH Hazardous Drugs List ?** yes | no | **Comments** |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Enablex | darifenacin HBr | | | |
| Epogen** | epoetin alfa | | | |
| Eraxis | andulafungin | | | |
| Ethyol | amifostine | | | |
| Exjade | deferasirox | | | |
| Focalin | dexmethyphenidate HCl | | | |
| Fortovase** | saquinavir mesylate | | | |
| Fosrenol | lanthanum carbonate hydrate | | | |
| Gabitril | tiagabine | | | |
| Herceptin | trastuzumab | | X | Refer to letters to NIOSH from Dr. Gene Murano, Vice President, Regulatory Affairs (January 7, 2004) and Debora Van der Sluis, Environment, Health and Safety (April 12, 2004) |
| Humira | adalimumab | | | |
| Hydase** | hyaluronidase | | | |
| Invirase** | saquinavir mesylate | | | |
| Iplex | mecasermin rinfabate | | | |
| Januvia | sitagliptin phosphate | | | |
| Ketek | telithromycin | | | |
| Lamictal | lamotrigine | | | |
| Levemir | insulin detemir | | | |
| Lucentis | ranibizumab | | X | |
| Lumigan | bimatoprost | | | |

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| **Proprietary Name** | **Established Name** | **Should this Drug be Included in the NIOSH Hazardous Drugs List ?** | | **Comments** |
| | | **yes** | **no** | |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Macugen | pegaptanib sodium | | | |
| Magnevist | gadopentetate dimeglumine | | | |
| Metadate* | methyphenidate HCl | | | |
| Methylin* | methylphenidate HCl | | | |
| Multihance | gadobenate dimeglumine | | | |
| Naglazyme | galsulfase | | | |
| Nevanac | nepafenac | | | |
| Nexium | esomeprazole magnesuim | | | |
| Noxafil | posaconazole | | | |
| NutreStore | L-glutamine | | | |
| Omacor | omega-3-acid ethylesters | | | |
| Opana | oxymorphone HCl | | | |
| Pentetate Zinc Trisodium | | | | |
| Prevacid NapralPAC | lansoprazole; naproxen | | | |
| Prezista | darunavir | | | |
| Prialt | ziconotide | | | |
| Procrit** | epoetin alfa | | | |
| Propanolol HCl | | | | |
| Ranexa | ranolazine | | | |
| Raptiva | efalizumab | | | |
| Remicade | infliximab | | | |
| Ritalin* | methylphenidate HCl | | | |

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| **Proprietary Name** | **Established Name** | **Should this Drug be Included in the NIOSH Hazardous Drugs List ?** | | **Comments** |
| | | **yes** | **no** | |
| **New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs** | | | | |
| Sanctura | trospium chloride | | | |
| Sensipar | cinacalcet HCl | | | |
| Serzone | nefazodone HCl | | | |
| Strattera | atmoxetine HCl | | | |
| Symlin | pramlintide acetate | | | |
| Trasylol | aprotinin | | | |
| Tyzeka | telbivudine | | | |
| Vectibix | panitumumab | | | |
| Ventavis | iloprost | | | |
| Veregen | kunecatechins | | | |
| VESIcare | solifenacin succinate | | | |
| Videx | didanosine | | | |
| Visudyne | verteporfin | | | |
| Vitrase | ovine hyaluronidase | | | |
| Wellbutrin** | bupropion HCl | | | |
| Xifaxan | rifaximin | | | |
| Zarontin | ethosuximide | | | |
| Zinecard | dextrazoxane | | | |
| Zyban** | bupropion HCl | | | |
| Zyprexa | olanzapine | | | |
| | | | | |
| * = several proprietary names for same drug; ** = two proprietary names for same drug | | | | |

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| Proprietary Name | Established Name | Should this Drug be Included in the NIOSH Hazardous Drugs List ? yes | no | Comments |
| New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs | | | | |
| ADDITIONAL COMMENTS | | | | |