DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Immunization Program

Date: **August 13, 2018**

To: All Immunization Providers

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Subject: **2017 China DTaP recall**

PLEASE POST FOR ALL IMMUNIZATION PROVIDERS

Background

On October 31st 2017, China FDA recalled 650,000 doses of DTaP vaccine from 2 domestic, private-sector vaccine manufacturers:

- Wuhan Biological Products Research Institute Co., Ltd – batch number: 201607050-2
  - 400,000 doses
- Changchun Changsheng Company – batch number: 201605014-01
  - 250,000 doses

The recall is not a safety issue, however there is concern regarding inadequate protection due to low potency of vaccine components:

- Pertussis potency was low in both companies' vaccine
- Tetanus toxoid potency was low in Changchun Changsheng's vaccine
- The diphtheria component met standards in in both companies' recalled DTaP

China National Drug Administration released these two vaccine lots, which were distributed to Shandong, Chongqing, and Hebei provinces between March 2017 and May 2017.

Of the 650,000 doses, 614,000 were administered to infants and children using the routine immunization schedule of DTaP at 3, 4, 5, and 18 months of age (there is a DT booster at 6 years of age). Most children (400,000) received 1 dose of the implicated vaccine; 80,000 received 2 doses; and 17,000 received 3 doses.

Because of the timing of vaccine distribution and the timing of recall (5 to 8 months), children could have received sub-potent vaccine in the primary series or the 18-month booster dose, but not both.

Guidance

Review vaccine history of infants and children who have recently returned from China.

Check whether they received DTaP vaccine distributed between March 2017 and May 2017 in Shandong, Chongqing, or Hebei provinces from either of these 2 manufactures: Wuhan Biological Products Research (batch number: 201607050-2) or Changchun Changsheng Company (batch number: 201605014-01).

Any DTaP doses that were distributed between March 2017 and May 2017 in Shandong, Chongqing, or Hebei provinces should be considered invalid and these children need to be revaccinated. The vaccine record may not include vaccine manufacturer information; in these situations, we would recommend repeating the dose.